March 27, 2018 P.M.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In re: Bard IVC Filters, Products Liability Litigation	MD-15-02641-PHX-DGC
Sherr-Una Booker, an individual, Plaintiff, v. **C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,** Defendants.	Phoenix, Arizona March 27, 2018 1:00 p.m. CV-16-00474-PHX-DGC

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 9 P.M.

(Pages 2001 through 2160)

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March 27, 2018 P.M.

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I N D E X

TESTIMONY

E X H I B I T S

E X H I B I T S (Continued)

Number		Ident	Rec'd
7411	2008 Surgeon General's Call to Action re PE and DVT	2052	2054

MISCELLANEOUS NOTATIONS

Item	Page
Proceedings outside the presence of the jury	2113

RECESSES

	Page	Line
(Recess at 2:31; resumed at 2:44.)	2059	7
(Recess at 4:24; resumed at 4:34.)	2113	2

P R O C E E D I N G S 12:58:34

(Jury enters at 1:00.)

(Court was called to order by the courtroom deputy.)

(Proceedings begin at 1:01.)

THE COURT: Thank you. Please be seated. 01:01:07

You may continue, Mr. Johnson.

MR. JOHNSON: Thank you.

(CLEMENT GRASSI, M.D., a witness herein, was duly sworn or affirmed.)

CROSS - EXAMINATION (Continued) 01:01:12

BY MR. JOHNSON:

Q. Dr. Grassi, when we broke for lunch, we were talking about the uses of the, SIR information by manufacturers by Bard's and we were about to play a clip from your deposition that was given in July of 2014. 01:01:31

MR. JOHNSON: With the Court's permission, I would like to play his testimony at page 89.

THE COURT: All right.

(Video clip of Dr. Grassi's deposition was played.)

BY MR. JOHNSON: 01:02:34

Q. Doctor, with respect to your work on the SIR committee, you folks did not study a situation where there was a cascading set of adverse events where a filter migrates in a caudal fashion leading to tilt, leading to multiple perforations of the vena cava, leading to multiple penetrations of nearby vital 01:02:57

structures, leading to multiple fractures of the filter and filter fragment embolization, that was that you never studied by you in your committee; correct? 01:03:03

A. No. There was never the studying of that specific multiple part example that you just mentioned. We dealt with individual topics. They were included in what you described. 01:03:21

Q. You looked at individual adverse events, not a cascading series of adverse events greed?

A. Agreed.

MR. JOHNSON: Greg. If you would pull up Exhibit 6842 again, page 13. 01:03:46

BY MR. JOHNSON:

Q. And doctor, with respect to that table, we've already established that the other trackable events that are referenced in here and the reported rates are not the SIR standard for complications. But your committee I believe also established that the rate of clinically significant penetration is not precisely known. Would you agree with that? 01:04:01

A. If I may clarify your question. My committee prior to the 2001 guidelines? 01:04:25

Q. Yes, sir.

A. And what was your question again, please.

Q. If you would look at your screen, I think you'll understand the question. There was never a determination by any SIR committee regarding the rate of clinically significant 01:04:37

penetrations because that was not precisely known? 01:04:41
A. I'll say this, that the rate of IVC penetration described on this standard which is a newer standard table than my own, is quoted as the 100 percent rate; and when we reviewed it prior to 2001, we based our rates upon what was available in 01:05:04
the medical literature.
Q. Well, if it wasn't precisely known in 2016, would you agree it probably wasn't known back when you and your committee met?
A. I'm not quite sure I understand exactly what you mean by 01:05:23
"not precisely known."
Q. Well, the 2016 committee stated that the rate of clinically significant penetration is not precisely known. I assume you understand what that phrase means?
A. Yes. I'll take your word for that. 01:05:44
Q. Okay. If it wasn't known in 2016, can we agree it probably wasn't known by you and your committee members back in the early 2000s?
A. I think we can agree that as we said in the guidelines of 2001 that there was a range over which -- a range over which 01:06:04
penetration had been observed in the medical literature and also by people working on the committee.
Q. And just so we understand this literature review that you and your committee did, you folks just surveyed articles that were not Level 1 articles and you reported what amounts to a 01:06:24

low and a high. There's -- there was no averaging, there was no statistical analysis that was done; agreed? 01:06:29

A. No. I wouldn't agree with that. We surveyed the world literature that was known at that time and as I mentioned, although there were set references and citations quoted in the 2001 guidelines, the process started by reviewing literally hundreds of different articles in the world literature. 01:06:45

Q. But all you folks ended up doing was reporting what the low rate was and the high rate?

A. That's correct for the purpose of this table. 01:07:08

Q. All right. Because common sense tells us, does it not, that you, Dr. Grassi, and any other reasonable interventional radiologist would not put a filter in that has a clinically significant penetration rate of 100 percent. Agreed?

A. Yes. I think that's fair. It would be logical to turn to a device that had a better rate. 01:07:26

Q. And the disclaimer that we have been talking about that's found at the bottom of that table indicating that the SIR standard for complications is not set forth in this table was created because manufacturers were improperly using this information. Would you agree? 01:07:44

A. No, I can't offer that opinion. I can't essentially say whether manufacturers were using it correctly or not correctly. I can just say based on the data, what I knew from our investigation. 01:08:07

Q. Okay. We're coming down the home stretch. I've got a couple more questions. We talked about the fact that there has never been a long-term Level 1 safety study for Bard G2 Filters. We've established that. Do you agree? 01:08:08

A. Yes. 01:08:23

Q. And when we do or -- I'm sorry, not when we do. But when a safety study is done of that nature, there are strict controls that are in place to include safety controls. Agreed?

A. It would depend upon the exact study design.

Q. But typically there would be monitoring, there would be protocols in place to look for problems that might in some fashion jeopardize the safety and the well-being of the patients that are in that study. Would you agree with that? 01:08:43

A. Well, let me say in answer to your question in the upcoming Preserve Trial -- 01:09:05

Q. Sir, I'm not asking about the Preserve Trial. I'm asking conceptually about safety studies.

A. In answer to your question, in many studies, both from the start of the study design and also because of hospital policy and regulations, there is a safety factor built in so that patients who participate in these studies can do so freely, voluntarily, and not be concerned about poor safety events. 01:09:21

Q. This is a yes-or-no question. Are you aware that with respect to the G2 filter, this filter was tested in sheep, it was tested on the bench in PVC piping with sausage casing, and 01:09:48

from there, it went to the real world and it was implanted in people like Ms. Booker? 01:09:53

A. I'm not aware of those sequence of events.

Q. If that happened, would you agree that would be a human experiment? 01:10:11

A. In fairness, that's a hypothetical question and I can't really ask -- answer a purely hypothetical like that.

Q. Okay. Thank you very much.

THE COURT: Redirect?

MR. NORTH: No, nothing further, Your Honor. 01:10:26

THE COURT: All right. Thank you, sir. You can step down.

THE WITNESS: Thank you.

(Witness excused.)

MS. HELM: Your Honor, at this time we call Dr. Scott Trerotola by deposition -- by video deposition. Scott Trerotola is a medical doctor who is a board certified radiologist with a specialty in interventional radiology. He maintains a clinical practice in interventional radiology at the Hospital of the University of Pennsylvania where he has been Chief of the Interventional Radiology Department since 2001. He graduated from the University of Pennsylvania Medical School in 1986 and has been implanting IVC filters since the 1990s and retrieving optional IVC filters since they first came on the market in the early 2000s. 01:10:44 01:11:13 01:11:40

(Whereupon the video deposition of Dr. Trerotola was played.) 01:13:38

THE COURT: Is that the end?

MS. HELM: Yes, Your Honor.

Your Honor, at this time we call Dr. Daniel Cousin. 01:23:29

Your Honor, before Dr. Cousin takes the stand, we would like to admit 6825 which is part of Ms. Booker's medical record that has previously been stipulated to and has been provided to the plaintiffs.

MR. JOHNSON: Is that the ER record? 01:23:56

MS. HELM: No. It's that --

MR. JOHNSON: No objection.

THE COURT: What's that number?

MS. HELM: 6825.

THE COURT: All right. That document is admitted. 01:24:04

(Exhibit Number 6825 was admitted into evidence.)

COURTROOM DEPUTY: Doctor, if you'll please come forward and raise your right hand.

(DANIEL COUSIN, M.D., a witness herein, was duly sworn or affirmed.) 01:24:11

COURTROOM DEPUTY: Please have a seat, sir.

MS. HELM: Your Honor, may I consult with Mr. Johnson about one redaction before we get started?

THE COURT: Yes.

(Counsel confer.) 01:25:00

MS. HELM: Thank you, Your Honor. We were able to resolve that. 01:25:22

DIRECT EXAMINATION

BY MS. HELM:

Q. Dr. Cousin, would you please introduce yourself to the jury. 01:25:26

A. Sure. My name is Daniel Cousin. I'm a diagnostic radiologist.

Q. And Dr. Cousin, where did you go to college?

A. Harvard University. 01:25:37

Q. And what was your major at Harvard?

A. It was cognitive neuroscience. It was a double major, joint honors between biology and psychology.

Q. And after college did you attend medical school?

A. Yes. 01:25:51

Q. And where did you go to medical school?

A. Albert Einstein.

Q. And where is Albert Einstein Medical School?

A. New York.

Q. And following medical school, did you continue to pursue your training in medicine? 01:25:59

A. Yes.

Q. And what was your next training after medical school?

A. I did my internship. That was at Mt. Sinai's internship program, also in New York. 01:26:10

Q. And what was that in? 01:26:16
A. Internal medicine.
Q. And following your internship in internal medicine, did you pursue a residency in diagnostic radiology?
A. Yes. 01:26:25
Q. And where did you complete -- where did you do your residency in diagnostic radiology?
A. Sure. I went to the Yale Norwalk program to do the first two years of my radiology residency and then I completed the last two years of my radiology residency at University of 01:26:40
Florida Shands Hospital in Gainesville.
Q. And why did you move back to Florida in the middle of your residency?
A. Family.
Q. And following your residency, were you licensed or during 01:26:51
your residency, were you licensed as a medical doctor --
A. Yes.
Q. -- in the state of Florida?
A. Yes.
Q. Are you also licensed as a medical doctor in the state of 01:27:00
New York?
A. Yes.
Q. And I interrupted your training. After you finished your residency at the University of Florida Medical Center, did you
pursue further training? 01:27:12

A. Yes. 01:27:14
Q. And where was that?
A. I did a fellowship at Columbia in New York City.
Q. And what was the emphasis of your fellowship?
A. The emphasis was whole body imaging including PET, CT and 01:27:25
nuclear radiology.
Q. While you were at Columbia pursuing your fellowship, did you work as a radiologist?
A. While I was in training?
Q. Yes. 01:27:42
A. Yes.
Q. And where did you work as a radiologist when you were at Columbia?
A. Well, as part of the training itself, I worked as a
radiologist; and after that I stayed in the Columbia system and 01:27:52
worked at Columbia's Harlem affiliate. I was the program director for the Radiology Residency Program.
Q. And once you finished working with -- in Harlem in the radiology program, did you move back to Florida?
A. Yes. 01:28:14
Q. During your training in medical school and in your residency and your fellowship in diagnostic radiology, were you trained and made aware of IVC filters?
A. Yes.
Q. Are you an interventional radiologist? 01:28:28

A. No. I have interventional radiology training but it's not part of my active daily practice. 01:28:30

Q. Your active daily practice is that of a diagnostic radiologist; right?

A. Yes. 01:28:39

Q. Would you explain to the members of the jury what a diagnostic radiologist does, please.

A. Sure. While I do some light interventional procedures, my main focus of what I do from day to day is to interpret CT, x-ray, MRI, mammograms, DEXA scans, fluoroscopy. These are each different modalities in radiology. 01:28:55

Q. And are those scans x-rays, CT scans, MRIs, are those things that are ordered by physicians who are hands-on treating patients?

A. Yes. 01:29:16

Q. And is it your responsibility as a diagnostic radiologist to provide information to those treating physicians so that they can accurately diagnose the patient and work with the patient on medical options?

A. Yes. 01:29:28

Q. Are you board certified?

A. Yes. I'm certified by the American Board of Radiology and also by the National Board of Physicians and Surgeons.

Q. Okay. And what does it mean to be board certified?

A. There's a series of tests that you have to pass. 01:29:45

Q. Do you currently practice diagnostic radiology on a day-to-day basis today? 01:29:52
A. Yes.
Q. And where do you practice?
A. Currently I am the clinical director at Bayview Radiology in Tampa. 01:29:59
Q. Is that a hospital-based radiology practice?
A. No.
Q. Is it an outpatient-based radiology practice?
A. Yes. 01:30:11
Q. What is the difference -- some radiologists practice in hospitals; correct?
A. Correct.
Q. What is the difference between what you do as an outpatient-based diagnostic radiologist and what a diagnostic radiologist does in a hospital? 01:30:22
A. They are pretty similar. We're seeing patients that can present with abnormalities and we have to just diagnose them and communicate these abnormalities, or lack thereof, to the ordering physicians. 01:30:42
Q. Dr. Cousin, you also do some work with what we call medical-legal work; is that right?
A. Where yes?
Q. And what is medical-legal work?
A. It's radiology consultation as applied to legal cases. 01:30:54

Q. And that's exactly what we asked you to do in this case; is that right? 01:31:02
A. Yes.
Q. You were retained by my law firm; is that right?
A. Yes. 01:31:08
Q. Prior to being retained to do some work on this case, had you ever worked with my law firm before?
A. No.
Q. Have you ever done any consultation for Bard?
A. No. 01:31:19
Q. Are you being paid by my law firm for your time?
A. Yes.
Q. Do you know the total charges that you have charged us for your work?
A. Not off the top of my head. 01:31:29
Q. What were you asked to do in this case as it pertains to imaging taken of Ms. Booker?
A. I was asked to look at the imaging and determine whether or not it was interpreted correctly.
Q. Were you specifically asked to look at an x-ray taken in March 2009 at Lincoln Memorial Hospital? 01:31:47
A. Yes.
Q. And Lincoln Memorial Hospital is in New York; correct?
A. I believe so.
Q. Is the standard of care for radiologists in New York the 01:32:01

same as the standard of care for radiologists in every other state in the United States? 01:32:05

A. Yes. The standard is the same.

Q. And we've talked about standard of care. What does that mean? 01:32:14

A. Well, what would be expected to be performed by a reasonably prudent radiologist.

Q. And before we go forward and get into your opinions, would you explain to the jury what an incidental finding is in the world of diagnostic radiology? 01:32:35

A. Sure. An incidental finding is one that may not be the reason for the study but you happen to see it and it's important and many times that you report it.

Q. Does the standard of care for a diagnostic radiologist require that the diagnostic radiologist report incidental findings? 01:32:53

A. Yes, but only if they are important to be reported.

Q. And how do you make that determination of whether they are important or not?

A. If there is something that you happen to see that could have potentially negative effects, if you don't report it, then I would consider that to be important. 01:33:06

Q. As a diagnostic radiologist in examining or reviewing x-rays, CT scans, MRIs and the other type of imaging that you review, have you seen implanted devices in patients? 01:33:27

A. Yes. 01:33:32
Q. As a diagnostic radiologist, do you need to know the purpose of a device to be able to determine whether its appearance is normal or abnormal?
A. Not really. I mean, by looking at the device, you often know what the purpose is but the answer to your question is you don't have to know. 01:33:44
Q. You said you're a member of the American College of Radiology. Did I get that right?
A. Yes. 01:34:00
Q. If the American College of Radiology says that it can be difficult to find incidental findings on an x-ray or CT scan, do you agree that all incidental findings are difficult to find?
A. No, not at all. 01:34:16
Q. Are there incidental findings that are very obvious?
A. Absolutely.
Q. Did you form an opinion in this case about whether Dr. Amer, who read the x-ray of Ms. Booker on March 26, 2009, complied with the standard of care for diagnostic radiologists? 01:34:36
A. I did form an opinion.
Q. And what is your opinion?
A. My opinion is that the read was below the standard of care.
Q. So it's your opinion he did not comply with the standard 01:34:46

of care; correct? 01:34:48
A. That's correct.
Q. In forming that opinion, did you review medical records in this case?
A. I did. 01:34:57
Q. Did you review the emergency room record for Ms. Booker at Lincoln Medical and Mental Health Center on March 26, 2009?
A. I believe so.
MS. HELM: Can we pull up 6667, please.
Your Honor, this is already in evidence I believe? 01:35:16
THE COURT: Let's have Traci confirm that.
COURTROOM DEPUTY: 6667?
MS. HELM: Yes, ma'am.
COURTROOM DEPUTY: No.
MS. HELM: It's not in evidence? 01:35:36
COURTROOM DEPUTY: No, ma'am.
THE COURT: Actually, Traci, my notes show it was.
COURTROOM DEPUTY: I apologize. It was admitted on the 22nd.
THE COURT: It is in evidence. 01:35:46
MS. HELM: Your Honor, may I display to it jury?
THE COURT: You may.
BY MS. HELM:
Q. Dr. Cousin is this the emergency room record for Ms. Booker for March 26, 2009, from Lincoln Medical Center that you 01:35:54

reviewed? 01:35:59
A. I believe so.
Q. And specifically on her admission in the hospital on March 26, 2009, down towards the bottom, do you see where the emergency room doctor indicated had IVC filter placed as well? 01:36:10
A. Yes, I do.
Q. So based on that, is it your understanding that either Ms. Booker told or somehow the emergency room doctor was aware that Ms. Booker had an IVC filter?
A. Yes. 01:36:35
Q. And if you would turn to page four, please. And on page four, under Assessment, did the emergency room doctor order a lumbar x-ray of Ms. Booker?
A. Yes.
Q. And did you have an opportunity to review you that x-ray report in forming your opinions in this case? 01:36:55
A. Yes, I did.
Q. Would you please pull up 6668?
MS. HELM: And, Your Honor, I'm sure this one is in evidence only to stand corrected. 01:37:08
COURTROOM DEPUTY: It's in evidence, yes.
MS. HELM: May I publish 6668 to the jury, Your Honor?
THE COURT: Yes.
\\\

BY MS. HELM: 01:37:20
Q. Dr. Cousin, is this the x-ray report for the lumbosacral spine x-ray of Ms. Booker taken on March 26, 2009?
A. Yes.
Q. And did you review this in forming your opinion? I already asked you that. 01:37:28
A. Yes, I did.
Q. Okay. Would you report to the jury what Dr. Amer stated in his report about the condition of Ms. Booker's spine?
A. Sure. I'll just read the report: Multiple views of the lumbosacral spine demonstrate normal disc spaces. The spinous processes and pedicles are within normal limits. There is no evidence of fracture or dislocation. The vertebral body heights are well-preserved. Soft tissues are unremarkable. 01:37:43
IVC filter is noted. 01:38:06
Q. So you just read that Dr. Amer stated "IVC filter is noted"; is that right?
A. Yes, I did.
Q. And making a statement that the IVC filter is noted, what did Dr. Amer tell Ms. Booker's treating physician at Lincoln Medical about the condition of her filter? 01:38:15
A. That there's no abnormality essentially. It's describing a normal -- that you think it's a normal study.
Q. Okay. He did not tell her treating physician that the filter had any abnormality at all; correct? 01:38:36

A. That's right. 01:38:39
Q. Okay. Did you have an opportunity to look at the actual x-rays taken by Dr. Amer on March 26, 2009?
A. Yes.
MS. HELM: Would you please pull up 6825? 01:38:49
Your Honor, this was admitted immediately prior. May we publish this to the jury?
THE COURT: Yes.
BY MS. HELM:
Q. Dr. Cousin, are these two of the views of the x-rays taken 01:39:05
by Dr. Amer on March 26, 2009, of Ms. Booker at Lincoln Medical Center in New York?
A. Yes. They are two of the four views.
Q. Two of the four views. And in forming your opinion on the standard of care, what do you see on this x-ray that makes you 01:39:24
believe that Dr. Amer did not comply with the standard of care when he stated "IVC filter is noted"?
A. The reason why I say this is because you can see the IVC filter very clearly. However, there is one strut that is not like the others. 01:39:45
MR. JOHNSON: Excuse me, Your Honor. We need to approach. This is not in his report. It's not in his testimony. I know where he's going.
THE COURT: Well, let's bring the reports with us.
(At sidebar 1:40.) 01:40:03

THE COURT: What is not in the report? 01:40:19

MR. JOHNSON: He's about to describe a fracture --

MS. HELM: No, he's not. No, he's not.

THE COURT: Tell us where you're going with it.

Hold on. 01:40:28

MS. HELM: All he's going to say is that the strut pointing straight up is an abnormality of the filter that shows it's not like the others and it should have been reported. That is all he's going to say. He is not going to say it's fractured. 01:40:38

THE COURT: All right.

MR. JOHNSON: Your Honor, I don't see that in here.

THE COURT: Can you show me where that is in your report?

MS. HELM: Yes. 01:40:54

MR. JOHNSON: It's right here. There's no interpretation of it.

THE COURT: Okay. So tell me what you're going to elicit besides that statement.

MS. HELM: Nothing. 01:41:08

MR. JOHNSON: He's going to describe a strut that is --

THE COURT: Well, he can say there's a prong that extends towards the abdominal aorta. That's clearly within his report. 01:41:21

MR. JOHNSON: Okay. 01:41:21

MS. HELM: He's not going to say it's fractured, Joe.

THE COURT: Okay. Well I think she can ask the question. If you think the answer is inappropriate in light of this, let me know. 01:41:30

Is there anything else in the report on this subject?

MS. HELM: The violation of the standard of care.

THE COURT: Okay. But in terms of describing the x-ray that is in the report.

MS. HELM: Yes, but he was asked about the x-ray in his deposition. 01:41:41

THE COURT: And what did he say?

MS. HELM: That it shows an abnormality which is all he's going to say today.

THE COURT: Okay. 01:41:49

MR. JOHNSON: But as long as we're not going to say there's a fracture.

MS. HELM: He is not going to say there's a fracture.

THE COURT: Okay.

(End of sidebar discussion.) 01:41:57

THE COURT: Thank you.

BY MS. HELM:

Q. Dr. Cousin, referring back to 6825 and the appearance of the filter, does the x-ray and the two views of the x-ray shown on 6825 show and demonstrate an abnormality in the filter? 01:42:22

A. Yes, it does. 01:42:29
Q. And was that abnormality in the filter -- and are you talking about the strut that is pointing up towards the aorta while the others are pointing down?
A. Honestly, I think it's -- the lights here would be better if we turned them off if we were looking up there. 01:42:39
THE COURT: They have all got screens in front of them.
BY MS. HELM:
Q. Dr. Cousin, are you talking about one strut that is pointing in the opposite direction of all the others? 01:42:47
A. Yes, I am.
Q. And did Dr. Amer report to Ms. Booker's treating physicians the condition of the strut pointing in the opposite direction of all the others of the IVC filter? 01:43:04
A. No. There was no abnormality described involving the filter.
Q. Okay. And why was it a violation of the standard of care to fail to describe the abnormality in the condition of Ms. Booker's filter? 01:43:17
A. The reason why it's below the standard is because this is a pertinent finding. First of all, it's a prominent finding to the eye that you can see when one of the struts is up and all the others are down so it jumps out at you. And the second reason is because it has potential worrisome consequences if 01:43:40

something were to happen involving where that strut were to embolize to, for example, and for the fact that the device may not function properly if it's broken. 01:43:48

Q. Did Ms. Booker's treating physician at Lincoln Medical have the necessary information to assess her medical condition regarding her IVC filter on March 26, 2009, based on Dr. Amer's report stating IVC filter is noted? 01:44:06

A. No. The read did not characterize appropriately the findings that were present at the time.

Q. Now, Dr. Cousin, you would agree that because he was looking at her spine, the presence of the IVC filter and the condition of the IVC filter would be an incidental finding? 01:44:29

MR. JOHNSON: Leading, Your Honor.

THE WITNESS: Technically --

THE COURT: Hold on. 01:44:45

Sustained.

BY MS. HELM:

Q. Dr. Cousin, was the abnormality in the IVC filter an incidental finding?

A. It was an incidental finding in that the indication for the study wasn't, for example, evaluate the filter. It was back pain, something to that effect. So technically it's an incidental finding. 01:44:53

Q. Based on your experience as a diagnostic radiologist, is that an incidental finding that was difficult to see? 01:45:11

A. No. I do not believe that was difficult to see. 01:45:14
Q. Based on your experience as a diagnostic radiologist, is that an incidental finding that should have been reported?
A. Yes.
Q. And based on your experience as a diagnostic radiologist, 01:45:25
was it below the standard of care to fail to report that incidental finding to Ms. Booker's treating physicians?
A. Yes.
Q. Dr. Cousin, are all the opinions you offered today offered to a reasonable degree of medical certainty? 01:45:42
A. Yes.

MS. HELM: Nothing further, Your Honor.

THE COURT: Cross-examination?

MR. JOHNSON: Yes, sir.

CROSS - EXAMINATION 01:45:57

BY MR. JOHNSON:
Q. Good afternoon, Dr. Cousin.
A. Hell local.
Q. I think I heard you say that you practice in Florida?
A. I practice in Florida. 01:46:02
Q. As a diagnostic radiologist; is that correct?
A. Correct.
Q. And you used the term "imaging studies" and I want to make sure everybody understands what that is. That would be the full compliment of what we call x-ray type studies ranging from 01:46:14

plain x-rays to CT scans, to MRIs as examples? 01:46:20
A. You say x-ray type studies?
Q. Yes.
A. Some of them use sound waves like ultrasounds. Some of them use x-rays like CT and radiography. Some of them use magnets like MRI. 01:46:32
Q. All right. But it does include x-rays, MRI, and CT imaging?
A. Yes.
Q. As I understand it, you do not in your private practice implant or remove IVC filters? 01:46:43
A. Correct.
Q. You never published anything about IVC filters; correct?
A. No.
Q. You are employed in Tampa, Florida, at a family-owned business. I believe your father owns that business? 01:46:55
A. Yes.
Q. All right. And you are not on staff at any hospital in the state of Florida; is that correct?
A. I don't believe so. 01:47:11
Q. All right. And unlike working at the family business, in order to read imaging studies at a hospital, you have to make application and be credentialed; correct?
A. I'm sorry?
Q. In order for a doctor to read imaging studies at a 01:47:27

hospital in Florida, that doctor would have to make an application and would have to be accepted on staff at that hospital? 01:47:30

A. I believe so. It's up to the hospital.

Q. All right. That is you don't just show up and say, "Hello, everybody. I'm Dr. Cousin and I would like to come in and start reading x-rays." You don't do that? That's not the way it's done? 01:47:43

A. Correct.

Q. All right. And the Bayview Radiology where you work does not have any contracts with hospitals to read imaging studies in Florida; is that right? 01:47:53

A. Correct.

Q. Your contracts are with insurance companies?

A. Correct. We also have contracts with other providers as well. 01:48:09

Q. And just so we're clear, you've never set foot in a hospital in Florida as a private practice physician to read any imaging studies. Is that a fair statement?

A. In Florida only or also in New York? 01:48:30

Q. In Florida.

A. Not as a credentialed radiologist, just as a consultant.

Q. Sir, and when Ms. Booker was implanted with her filter in 2007, you had not yet graduated medical school; is that correct? 01:48:50

A. That's correct. Oh, no, that's not correct. No. I graduated medical school in 2005 so, yes, I had graduated. 01:48:53

MR. JOHNSON: Can we look at page 168 of the deposition given by Dr. Cousin?

And with the Court's permission, I would like to play the video clip from page 168. 01:49:22

THE COURT: You may.

(Video clip of Dr. Cousin's deposition played.)

BY MR. JOHNSON:

Q. As part of your private practice, you're not involved in the decision to monitor patients with filters, nor are you involved in the decision whether to remove the filter; is that correct? 01:49:47

A. I'm still going back to trying to understand that clip. I feel like maybe we talked after that about the clarification. It's just a moment in time. 01:50:01

I'm sorry. Let me go on to your next question.

Q. Sure. In your private practice, you are not involved in the decision whether to monitor a patient that has an IVC filter or whether to remove that filter. Is that a fair statement? 01:50:20

A. Correct. I currently am not doing that aspect of clinical radiology.

Q. All right. So you're not involved in performing the risk-benefit analysis to implant a filter or remove a filter. 01:50:32

Fair statement? 01:50:36

A. Correct. We can make recommendations but, like, for example, if I saw an abnormality, I might make a recommendation but as a general rule, we're not the ones who are finally making the ultimate decision with the patients and discussing 01:50:49 the risks and alternatives and benefits of one management decision or another.

Q. All right. And your assignment in this case was to look at a series of imaging studies to determine whether there were any abnormalities or misreads by radiologists interpreting 01:51:06 those studies; correct?

A. Yes.

Q. And I believe you looked at approximately six imaging studies, the first of which was performed in February of 2008, the last of the which was performed on December 2 of 2011 as 01:51:25 part of your assignment?

A. I would have to refer to my initial report. I don't have the dates memorized.

Q. All right. And I gather when you received this assignment, you knew there was a lawsuit? 01:51:39

A. That's usually what happens in these cases but I didn't really make any assumptions.

Q. And you would agree that back in 2009 Dr. Amer, who read the lumbar spine x-rays that you discussed a little while ago, at that time there was no lawsuit. You know that? 01:52:01

A. I really don't have an opinion on that. I was just asked to do something without being told anything about -- that there's a lawsuit. 01:52:03

Q. Was there any indication that Dr. Amer knew that there was a lawsuit? 01:52:14

A. I don't have any indication.

Q. Do you know whether there was any indication that Dr. Amer was aware of a problem with Ms. Booker's IVC filter?

A. I don't have any indication.

Q. And he was not looking specifically at the filter with respect to the x-ray study that he reviewed; correct? 01:52:30

A. Dr. Amer?

Q. Yes.

A. I don't really understand what you're saying.

Q. Sure. The reason for the x-ray was not to assess the filter. You would agree with that? 01:52:43

A. The reason -- the indication was not to assess the filter.

Q. All right. And with respect to your review of that x-ray, you don't even mention tilt in your report, do you?

A. In my report on this case? Did I mention tilt? 01:53:05

Q. Yes.

A. I did not mention tilt in my report.

Q. And do you know that this filter ultimately fractured at some point in time?

A. Yes. 01:53:18

Q. And you have no idea when it fractured, do you? 01:53:19
A. I don't really have an opinion on when it fractured.
Q. All right. And this was a plain x-ray that Dr. Amer looked at; right?
A. A plain x-ray? 01:53:33
Q. Yes.
A. Yes. There were four plain x-rays.
Q. There was absolutely no contrast that was used as part of this study?
A. Correct. 01:53:44
Q. And the x-ray does not define the inferior vena cava, the contours of that vessel, nor does it define the contours of the aorta which lies adjacent to the vena cava; is that correct?
A. Yeah. On x-ray you can't see soft tissues really well. You can only see hardware and high-density devices really well. 01:54:01
Q. All right. And for all you know, at that point in time, this filter or piece of it had fractured and had traveled to the heart? You don't know that?
A. Is that a question?
Q. Yes, it is. 01:54:24
A. Did I know that there was a fracture?
Q. No, sir. The question was: For all you know, a part of that filter had already fractured and a metal piece had already traveled to Ms. Booker's heart?
A. If that's the question you're asking me, I really don't 01:54:41

have an opinion on that. 01:54:43

Q. And I guess the point of my question is, you have no idea when the filter fractured and that one fragment then migrated to Ms. Booker's heart. That's a fair statement; correct?

A. I don't have an opinion on the chronology. I only have an opinion on the abnormality that we just looked at. 01:54:56

Q. All right. In your private practice as a diagnostic radiologist, am I correct that Bard has never provided you with any information to assist you when looking at x-rays and assessing filters that there's a relationship between tilt of the filter, perforation of the vena cava, penetration into adjacent vital structures, and fracture of the Bard G2 filter. Is that a correct statement? 01:55:15

MS. HELM: Your Honor, object. It exceeds the scope of the direct examination. 01:55:34

THE COURT: Sustained.

BY MR. JOHNSON:

Q. Doctor, you have not been provided as an expert with any Bard internal documents or internal information; is that correct? 01:55:46

MS. HELM: Your Honor, I object. Same objection.

THE COURT: Overruled.

THE WITNESS: I haven't been provided anything by Bard.

\\\

BY MR. JOHNSON: 01:55:57

Q. You have not even looked at the instructions for use or the IFU for the G2 filter implanted in Ms. Booker correct?

MS. HELM: Your Honor, same objection.

THE COURT: Sustained. 01:56:05

BY MR. JOHNSON:

Q. With respect to your criticisms of Dr. Amer, you have no idea how Ms. Booker's doctors would have treated Ms. Booker with respect to the abnormality you identified; is that correct? 01:56:27

A. I have no opinion on management or treatment options, just on the actual diagnostic evaluation.

Q. And you would agree with me that Dr. Amer did not cause the G2 Filter that was implanted in Ms. Booker to have this filter strut out of place and pointed in the direction of the aorta; correct? 01:56:45

A. Are you asking me if by reading the x-ray, Dr. Amer somehow caused the fracture -- the device to malfunction and break?

Q. That is another way to ask the question. 01:57:03

A. I do not believe that happened.

Q. All right. And you wouldn't feel very good, would you, doctor, if you were blamed by a filter manufacturer for a defective filter, would you?

A. I have no opinion on how I would feel. 01:57:23

Q. Would you -- you would not like to be blamed as a doctor if one of the devices you implanted in a patient was defective, would you? 01:57:28

A. I really don't have an opinion on that.

MR. JOHNSON: May I have one minute? 01:57:47

THE COURT: Yes.

MR. JOHNSON: That's all I have, Your Honor.

THE COURT: Redirect?

MS. HELM: No, Your Honor.

THE COURT: All right. Thank you, sir. You can step down. 01:58:22

(Witness excused.)

MR. NORTH: Your Honor, at this time the defendants would call Dr. Christopher Morris to the stand.

COURTROOM DEPUTY: Dr. Morris, if you'll come forward and stand right here and raise your right hand, please. 01:59:02

(CHRISTOPHER S. MORRIS, M.D., a witness herein, was duly sworn or affirmed.)

COURTROOM DEPUTY: Please have a seat, sir.

DIRECT EXAMINATION 01:59:21

BY MR. NORTH:

Q. Good afternoon, Dr. Morris. Could you tell the ladies and gentlemen of the jury, where you are from?

A. I'm from Burlington, Vermont.

Q. And what is your profession, sir? 01:59:39

A. Interventional radiology. 01:59:41
Q. And where do you work?
A. University of Vermont College of Medicine.
Q. And can you tell us a little bit about your educational background? 01:59:49
A. I went to medical school at Case Western Reserve University School of Medicine in Cleveland. From there I did my internship also in Cleveland at Case Western Reserve at Cleveland Metropolitan General Hospital. And then I went to Columbus, Ohio, at the Ohio State University Hospitals to do 02:00:03
diagnostic radiology residency. I ended up then doing my fellowship in vascular and interventional radiology at Mass General Hospital in Boston. And then ever since then I have been at the University of Vermont College of Medicine.
Q. In addition to a medical degree, did you obtain a master of science? 02:00:24
A. Yes, I did.
Q. And where was that from?
A. That was also at the Ohio State University.
Q. And in what area was the master of science? 02:00:31
A. It was in radiological sciences, primarily radiation biology and radiation physics.
Q. Can you describe the difference for us between diagnostic radiology and interventional radiology?
A. Certainly. Diagnostic radiology is a specialty involved 02:00:47

with making diagnosis through medical imaging and interventional radiology is a specialty that uses imaging techniques to perform minimally invasive procedures. 02:00:51

Q. And how long have you been practicing medicine?

A. Well, I have been at the University of Vermont for about 27 years, almost 27 years. But I started -- you know, after graduating in 1985, I have been practicing medicine to some degree so almost 33 years. 02:01:07

Q. So do you practice interventional radiology on a daily basis? 02:01:26

A. Yes, I do.

Q. And do you have any academic responsibilities?

A. Yes.

Q. And what are those?

A. I am a professor of radiology and surgery at the Larner College of Medicine at the University of Vermont. 02:01:31

Q. Are you licensed to practice medicine?

A. Yes.

Q. In what states do you have current licenses?

A. Active licenses in Vermont, New York, California. 02:01:44

Q. And do you have inactive licenses in several states?

A. Yes.

Q. And what are those?

A. Inactive in Ohio, Massachusetts, New Hampshire, and Nevada. 02:02:00

Q. Are you board certified? 02:02:04
A. Yes.
Q. In what areas?
A. I have a dual certificate in diagnostic radiology and vascular and interventional radiology. 02:02:10
Q. Are you a member of any professional societies?
A. Yes.
Q. And please tell us what those are.
A. Society of Interventional Radiology, American College of Radiology, Radiological Society of North America. I think 02:02:23
American Heart Association. I can't remember if -- if I'm still active in several others but I have been members of many others as well.
Q. Over the years, have you held any leadership positions within the Society of Interventional Radiology? 02:02:38
A. Yes. I am on the Standards of Practice Committee and several subcommittees of that committee. I was also the chair of the Inferior Vena Cava Filter Workshop during the mid-2000s and that lasted for three years.
Q. And what was the purpose or nature of that workshop? 02:02:57
A. That was a hands-on learning experience for participants at the annual Society of Interventional Radiologists. It basically taught interventional radiologists all the nuances about inferior vena cava filters.
Q. Describe for us just to little bit the nature of your 02:03:18

present clinical practice. 02:03:20

A. I'm a full-time interventional radiologist meaning a full-time clinical practice. Basically, every day except maybe occasionally one-half day a week, which we consider an academic day, I'm doing interventional radiology procedures. Another 02:03:36 half day a week I'm actually in our clinic seeing patients in our interventional radiology clinic. So the bulk of my time is actually the clinical practice of interventional radiology performing procedures on patients.

Q. What type of procedures do you perform on a routine basis? 02:03:54

A. We do more than 100 different discrete types of procedures. These are a wide variety of types of procedures. The commonly known types of procedures that I do include angioplasty of arteries and veins throughout the body except for the heart. Cardiologists do that. We do drainage 02:04:13 procedures of blocked organs, you know, blocked kidneys, percutaneous drainages of blocked liver ducts, things of that nature. We drain abscesses. We perform procedures such as vertebral augmentation. There's literally like over 100 types of procedures that require this image-guided technique that we 02:04:34 do.

Q. You mentioned that you started practicing medicine approximately 27 years ago. Can you estimate when you first began work with inferior vena cava filters?

A. When I was a first-year resident at the Ohio State 02:04:47

University residency so that would have been 1986. 02:04:50

Q. And in the roughly 27 years that have followed, have you continued to use inferior vena cava filters?

A. Yes.

Q. As a part of your medical practice, do you still treat patients with IVC filters today? 02:05:05

A. Yes.

Q. Have you published any medical articles during the course of your career?

A. Several. 02:05:18

Q. And do any of these publications involve inferior vena cava filters?

A. I think six or seven do, yes.

Q. Tell us some of the types of articles you've published.

A. The most recent was published in 2017 in a journal called "Vascular Medicine" and it had to do with follow-up of retrievable filters using a multidisciplinary system that we put in place beginning in 2006 and we showed that it doubled our retrieval rate of retrievable filters. 02:05:28

We were actually one of the first group to perform studies on the prophylactic use of filters in trauma patients in 19 -- that was published in 1993. 02:05:52

Q. Have you been retained by my law firm to consult with us regarding this litigation?

A. Yes. 02:06:10

Q. And do you charge for your consultation work? 02:06:11
A. Yes.
Q. What amount do you charge?
A. I charge a flat fee of $500 an hour.
Q. Prior to working as an expert witness in the area of IVC 02:06:19
filters with my firm, have you ever served as an expert witness in a case involving C.R. Bard?
A. No.
Q. Prior to working as an expert witness in the area of IVC filters, have you ever had a relationship with Bard where you 02:06:32
were paid by the company?
A. Yes.
Q. Tell us about that.
A. Briefly for a few years, in early 2000s to mid-2000s, I was a consultant for Bard and was there during the advent of 02:06:44
retrievable filters. And at that time, most interventional radiologists were not familiar with them. And so I acted as a clinical monitor which meant that I supervised the retrieval process. I went to University of Albany, Albany Medical Center and another hospital in Albany called St. Peter's and I 02:07:06
essentially taught them how to retrieve filters at that time.

I also gave a few talks around the region on retrievable filters sponsored by Bard but they were general talks about retrievable filters, you know, generically. And then I served on several focus groups for Bard, one was in 02:07:26

Chicago and another one was in I believe here in Scottsdale or Phoenix. 02:07:30

Q. And what filters was Bard selling at the time you were consulting with them?

A. It was certainly the Recovery early on and it may have extended into the years of the G2. 02:07:42

Q. Do you recall when the last time was that you received some payment from Bard for speaking or participating in meetings?

A. I can't remember exactly but I want to say around 2006. It could have been 2007 but probably 2006. 02:07:55

Q. Are you here today to provide opinions specific to Ms. Booker's medical course and treatment?

A. No.

Q. What are you here to talk about today, Dr. Morris? 02:08:14

A. Well, I have four opinions that I would like to express.

Q. Did you create a demonstrative slide that outlines those opinions?

A. Yes. Yes.

MR. NORTH: If we could pull up 7933. 02:08:30

Q. Doctor, why don't you summarize for the jury what your four opinions are in this litigation?

A. Well, pulmonary embolism is a significant public health problem and a life-threatening disease. IVC filters are effective in preventing PE deaths and this is specifically in 02:08:50

patients that have pulmonary embolism that can't receive anticoagulation. IVC filter risks are well-known and familiar by interventional radiologists. Those include thrombosis, not only of the inferior vena cava but the access site that we use to place the IVC filter. In addition, IVC filter complications -- 02:08:54 02:09:11

MR. O'CONNOR: Your Honor --

THE COURT: Excuse me, sir.

MR. O'CONNOR: No. I'm sorry. Go ahead.

THE WITNESS: -- complications include tilt, perforation, and penetration of the filter components, the migration of the filter, fracture, and then filter and fracture embolization, meaning moving to another location. 02:09:22

And then my last opinion is that the Bard G2 filter is safe and effective. 02:09:39

MR. O'CONNOR: Your Honor, I object to the last opinion. It's not disclosed anywhere in his report.

THE COURT: All right. Could you show me where that is in the report, Mr. North?

MR. NORTH: Yes, Your Honor. 02:09:52

Do you want me to just read the portion to you or show it to you?

THE COURT: You can just hand the report up.

MR. NORTH: In the second paragraph under the heading about Dr. Vogelzang there are several comments. 02:10:26

THE COURT: Okay. Hold on just a minute. 02:10:31
MR. O'CONNOR: What page?
MR. NORTH: Page 21.
THE COURT: The objection is overruled. The last opinion is disclosed in a long paragraph on page 21. 02:10:57
BY MR. NORTH:
Q. I'm sorry, Doctor, what was your fourth opinion?
A. That the Bard G2 filter is safe and effective.
MR. NORTH: Your Honor, at this time we would like to display Demonstrative Exhibit 7933 to the jury. 02:11:20
THE COURT: Any objection?
MR. O'CONNOR: No objection for a demonstrative.
THE COURT: You may.
MR. NORTH: Thank you, Your Honor.
BY MR. NORTH: 02:11:38
Q. Doctor, is this the slide that you prepared to summarize your opinions?
A. Yes.
Q. And does that set forth the four opinions you just stated for us? 02:11:44
A. Yes.
Q. Dr. Morris, tell us, turning to the first opinion about PE, what is a DVT?
A. A DVT stands for deep venous thrombosis and that represents clot formation in the deep veins of the legs or the 02:11:58

pelvis and that clot is clot that can stay local and it's commonly then referred to as DVT or it can break off and travel to the lungs and that is known as then a pulmonary embolism. 02:12:06

Q. And have you treated patients over the course of your practice who have DVT? 02:12:27

A. Yes.

Q. And have you treated patients who have pulmonary emboli?

A. Yes.

Q. Where do these large blood clots that become pulmonary emboli, where in the body do they usually originate? 02:12:39

A. They can originate lots of different places in the veins of the legs and the pelvis; but, generally, they are considered to be originating in smaller veins that propagate or extend into the larger veins. We call them proximal DVT, which are the most dangerous type of DVT, when they extend above the knee 02:12:59 joint. And when they extend into the big vein above the knee joint, called the femoral vein, or the big veins in the pelvis, called the iliac vein, they can be quite sizable. So at that point when they break off and cause a pulmonary embolism, that can be a major event for the patient. 02:13:17

Q. In the course of your career, have you had patients who have died from pulmonary embolism?

A. Yes.

Q. In the course of your career, are you aware of any of your patients who had a filter and, nevertheless, died from 02:13:29

pulmonary embolism? 02:13:33
A. Since 1981 we have placed roughly around 2000 filters and I cannot remember a PE after placing a filter in our patients. There may have been some incidental asymptomatic type of pulmonary emboli that have occurred that may have required, on 02:13:54
a very rare basis, a second filter. That's an indication for a second filter on top of the original filter, but those have been precious few and I can't even remember individual cases in that regard.
Q. Do you consider pulmonary embolism to be a significant 02:14:10
health risk in the American population?
A. Yes, I do.
Q. Do you have any information concerning how many deaths pulmonary embolism causes in this country per year?
A. Studies have shown that PE causes anywhere between 50,000 02:14:27
and 200,000 deaths annually in the United States and autopsy studies have shown that up to 10 to 11 percent of in-hospital or inpatient deaths are attributed to pulmonary embolism.
Q. When somebody has had one pulmonary embolism and then has a recurrent PE, what are the chances of death in that 02:14:52
circumstance?
A. I don't really know that statistic but if they have had a pulmonary embolism that is untreated, they are at risk of dying 30 percent of the time.
Q. And did you prepare a slide that summarizes some of these 02:15:16

statistics that you have just testified to? 02:15:19
A. Yes.
MR. NORTH: Your Honor, at this time we would like to show Exhibit 7933.0002 and we would like to publish this to the jury. 02:15:33
THE COURT: Any objection?
MR. O'CONNOR: Well, it's cumulative. The doctor just testified about this. It's a repeat of his testimony.
THE COURT: Objection overruled on that basis.
You can display it. 02:15:46
MR. NORTH: Thank you, Your Honor.
BY MR. NORTH:
Q. Are these the statistics you just were mentioning?
A. Yes.
Q. Explain to me again what this 10 to 11 percent that you mentioned of in-hospital deaths, what does that represent? 02:15:55
A. These are from some older autopsy studies where the investigators looked at a large number of deaths occurring in hospitalized patients and they found the cause of death to be 10 to 11 percent from pulmonary embolism in those patients. 02:16:20
Q. Which condition is more prevalent, DVT or PE?
A. DVT.
Q. And is there a reason for that?
A. Well, first of all, there can't be a pulmonary embolism unless there has been a precursor DVT. So it's the chicken or 02:16:36

the egg type of situation. And not all DVTs break off and travel to the lung and cause a pulmonary embolism. So it's just a matter of, you know, math trying to determine -- trying to realize that there are more DVTs than PE. 02:16:41

Q. What are some of the factors that increase the risk for pulmonary embolism? 02:16:58

A. There are many factors. One of the largest groups in the sort of the emerging knowledge about risk factors for DVT are in the genetics arena. And we call those patients that have a predisposition to develop clots patients that have a hypercoagulable state. So they, unfortunately, have inherited a gene that predisposes them to develop clots and particularly DVT. And some of these genes are called the protein S deficiency, protein C deficiency, Leiden V Factor. There's a whole slew of these genetic abnormalities. 02:17:18 02:17:40

So then the patients that don't have that genetic predisposition, that group includes any patient that's immobilized for a period of time, that immobilization may be as simple as, you know, being subjected to a long airplane ride or sick patients that are immobilized in a hospital bed. Trauma patients that are put to bedrest for a long time, spinal cord injury patients, those types. 02:18:01

And then another major group are cancer patients, either diagnosed or undiagnosed cancer. Certain cancers are even more prone to causing DVT than others. The cancers that 02:18:19

are really prone to developing DVT are those that involve the brain that interrupt what we call the blood brain barrier. It has something to do with releasing phospholipids into the bloodstream that becomes very thrombogenic to the patient. Urologic type cancers are also very thrombogenic, predispose patients to DVT. 02:18:23 02:18:35

And then the other group -- I mean, there's lots of other additional groups but injury and just in general like trauma, particularly trauma involving extremities also predisposes patients to DVT. 02:18:58

Q. What about bariatric surgery patients, are they at risk for pulmonary emboli?

A. Obesity is another one of those others that I mentioned briefly. That's another risk factor, yes.

Q. Has the federal government taken any action or made any pronouncement regarding the public health risk associated with pulmonary embolism? 02:19:19

A. Yes. In 2008 the U.S. Surgeon General submitted a call to action on pulmonary embolism and deep venous thrombosis.

MR. NORTH: If we could pull up Exhibit 7411. 02:19:41

BY MR. NORTH:

Q. Is this the Government publication that you just referenced?

A. Yes.

Q. And are you familiar with that publication? 02:19:57

A. I have read it. Not recently but I am familiar with it, yes. 02:19:59

MR. NORTH: Your Honor, we would tender 7411 as an exhibit.

MR. O'CONNOR: Objection. Hearsay, Your Honor. 02:20:12

THE COURT: What's your response, Mr. North?

MR. NORTH: 803(8) I believe is a public record.

THE COURT: Your response on 803(8), Mr. O'Connor?

MR. O'CONNOR: Well, Your Honor, I mean, is he going to just read from it or is he going to publish the entire 02:20:55 document?

THE COURT: He's moving the whole thing into evidence under 803(8).

MR. O'CONNOR: Objection. Lack of foundation, Your Honor. 02:21:07

THE COURT: Okay.

So are you changing the objection from hearsay to lack of foundation?

MR. O'CONNOR: Well, foundation for the public records exception hasn't been met. 02:21:19

THE COURT: Okay.

I'm going to overrule that. I think it is sufficiently authenticated under Rule 901(a) and, therefore, I'm going to overrule the objection based on lack of authentication and admit Exhibit 7411. 02:21:41

MR. NORTH: Thank you, Your Honor. 02:21:44

(Exhibit Number 7411 was admitted into evidence.)

MR. NORTH: If we could publish this to the jury, Your Honor.

THE COURT: You may. 02:21:53

BY MR. NORTH:

Q. So is this the publication we have been talking about from the Surgeon General?

A. Yes, it is.

Q. If we could turn to page nine. In the first paragraph, 02:22:03 about midway down the Surgeon General talks about estimates of PE. Do you see that?

A. Yes, I do.

Q. Is that generally consistent with your understanding of the current -- 02:22:23

A. Yes, it is.

Q. -- current rates in this country?

You told us just a few minutes ago I believe that you believe there are 50,000 to 200,000 deaths per year from PE in the United States. Here the Surgeon General says 100,000. We 02:22:38 have seen lots of different numbers. Do you have any idea why there is this large range of numbers here?

A. Well, different studies have used different, you know, parameters looking at those numbers and they have come up with different numbers. So, you know, some of the studies were done 02:22:56

quite a while ago and others more recently. So they have come up with a range of figures. 02:23:03

Q. If we could turn to page 11, please, and on the second paragraph, the Surgeon General here suggests that estimates indicate that PE causes more deaths each year than breast cancer, AIDS, or motor vehicle incidents, illnesses or injuries that are well understood. 02:23:30

Do you agree with that?

A. Yes, I do.

MR. NORTH: And then if we could turn to page 19. 02:23:50

BY MR. NORTH:

Q. Let me ask you this, Doctor. What is the standard treatment for pulmonary embolism?

A. Systemic anticoagulation.

Q. And in those patients where anticoagulation is not an option, what is alternative treatments that are available? 02:24:24

A. IVC filtration or an IVC filter.

Q. Tell me some of the specific patient types where you would recommend in your practice using an IVC filter.

A. I mentioned before that we would in the nineties and actually up to about the mid-2000s, one of our patient groups that we placed filters in were those that did not have a documented diagnosis of venous thromboembolism, meaning DVT or PE. Those are called prophylactic filters. But more than ten years ago we stopped placing IVC filters in that group for 02:24:51 02:25:16

various reasons. 02:25:19

And so we have restricted our indications to what I call the classic indications for IVC filtration. And those include patients that have a documented DVT or PE by imaging studies and that have either a contraindication to 02:25:35 anticoagulation or been on anticoagulation and then have a complication such as bleeding or those patients that have been treated initially with anticoagulation and then have a failure of anticoagulation, they either have another pulmonary embolism on therapeutic anticoagulation or their DVT extends 02:25:54 significantly above where it was even though they were on anticoagulation.

So complication, contraindication, or failure of anticoagulation.

Q. Is the inferior vena cava a stable part of the environment 02:26:13 in the anatomy?

A. That's sort of a difficult question to answer as far as stability. It is a thin-walled vascular structure. It is subjected to intraabdominal pressures more than, say, the thicker walled aorta but it does return blood from the lower 02:26:35 body to the heart. So I don't know if that is what you are referring to.

Q. Has the knowledge of the interventional radiology community concerning the anatomical environment of the dynamics of the inferior vena cava evolved over time? 02:26:56

A. It has been an evolution over many decades actually going back to the 1950s up until, you know, recent time periods. It has been a continuous area of investigation and interest and not only the interventional radiology community but surgery and other specialties as well. And the knowledge base keeps growing as we learn more information about the inferior vena cava. So it's like a lot of parts of medicine. We don't know everything about it and we continue to learn. It's called the evolution of scientific knowledge. 02:26:58 02:27:17

Q. Over the course of your career and your practice, have you had occasion to measure the pressures within the IVC? 02:27:35

A. Routinely, yes.

Q. And what sort of ranges have you found of pressures in your measurement of IVCs?

MR. O'CONNOR: Objection, Your Honor. Nondisclosure. 02:27:47

THE COURT: Is that in the report, Mr. North?

MR. NORTH: It's not specific. It's about his private practice.

THE COURT: Objection sustained.

BY MR. NORTH: 02:28:01

Q. Doctor, do you have an opinion to a reasonable degree of medical certainty as to whether inferior vena cava filters are effective in stopping clots?

A. Yes, I do.

Q. And what is that opinion? 02:28:11

A. That they are very effective in stopping clots in patients that cannot be anticoagulated who do have either a DVT or pulmonary embolism. 02:28:14

Q. And what is your opinion based on?

A. First and foremost, my personal experience and then review of the literature as well as speaking with colleagues that have similar experiences around the country, discussions and scientific colloquia and meetings and all of those types of venues. 02:28:27

Q. Do you also base your opinion on the medical literature? 02:28:49

A. Yes.

Q. In general, how does that help you form your opinion?

A. So that topic is very difficult to investigate as far as high-level scientific evidence, you know, Level 1 or Level 2 type studies because it would be unethical to do a randomized controlled trial of IVC filters versus no IVC filters because in patients that have pulmonary embolism because the group that would not receive an IVC filter would be subjected to about a 30 percent mortality rate and that would be untenable to perform a study like that. 02:29:08 02:29:31

So we have to rely on some other types of data to come to that conclusion. And the PREPIC 1 study was a study of permanent filters that was published in 1998 that looked at patients with proximal DVT, some of them also had PE but the common denominator was that they had proximal DVT. They were 02:29:54

all -- 02:29:57

THE COURT: Excuse me, Doctor, just because we're staying on a pretty firm schedule.

We're going to break, ladies and gentlemen, until 2:45. We'll excuse the jury at this time. 02:30:04

(Jury departs at 2:30.)

(Recess at 2:31; resumed at 2:44.)

(Jury enters at 2:44.)

(Court was called to order by the courtroom deputy.)

THE COURT: Thank you. Please be seated. 02:45:30

You may continue, Mr. North.

MR. NORTH: Thank you, Your Honor.

BY MR. NORTH:

Q. Dr. Morris, before the break, I believe you were talking about the PREPIC 1 study. How many PREPIC studies were there? 02:45:40

A. There have been two.

Q. And tell us about the second one if you could.

A. The PREPIC 2 was a study that came out a few years ago that looked at retrievable filters only, specifically one type of a filter called the ALN retrievable filter, and it was done 02:45:55 a little bit differently than the PREPIC 1 which was only dealing with permanent filters. PREPIC 2 looked at patients that are pulmonary embolism with several other criteria that they considered selection criteria. They looked at almost 400 patients, randomized them to filter and no filter and all of 02:46:20

those patients received anticoagulation just like PREPIC 1. 02:46:24

That does not represent the type of patients that we place filters in. We place filters in patients that can't receive anticoagulation but, as I mentioned before, to do a randomized controlled study of those two types of situations, 02:46:43 filter/no filter would be unethical so that's why they had to rely on the study design that they did.

The big difference between PREPIC 2 and PREPIC 1, because PREPIC 1 showed decreased pulmonary embolism with the filter group at day 12 and at eight years follow-up compared to 02:47:02 the group that did not receive a filter. So that showed that filters unquestionably, on top of anticoagulation, decrease -- the permanent filters decrease the pulmonary embolism rate.

In PREPIC 2 they did not look for pulmonary emboli. PREPIC 1 with the permanent filters, they did imaging on all 02:47:25 their patients either VQ radionuclide imaging or CT angiography looking for pulmonary emboli. And in PREPIC 2, they did not perform imaging. They only looked at symptomatic pulmonary embolism as their outcome.

So they did not show a benefit of IVC filters over no 02:47:44 IVC filters. But the study was not designed to look for pulmonary embolism. That was my main problem with the PREPIC 2.

Q. Has there ever been a Level 1 study conducted that compared a group of patients at risk for PE that received a 02:48:02

filter versus a group of patients at risk for PE who received no protection at all? 02:48:06

A. No, because that would be unethical to do.

Q. Have you reviewed additional literature regarding the effectiveness of IVC filters in reducing the number of pulmonary emboli? 02:48:19

A. Yes.

Q. And how would you characterize those studies?

A. Those studies were basically retrospective database studies. There's probably, you know, close to 10 of them that I reviewed and they invariably showed a benefit of IVC filters versus no filters by showing a decrease in the case fatality rate in the patients that received an IVC filter versus the ones that did not receive an IVC filter. 02:48:30

Q. And are all of those studies that you've reviewed on that topic, the efficacy of filters, published in the medical literature? 02:48:51

A. Yes.

Q. And are those published in peer-reviewed journals?

A. Yes. 02:49:06

Q. Did you prepare a slide that summarizes the filters -- I mean the articles that you have reviewed that talk about the effectiveness of filters?

A. Yes.

Q. Let's look at 7933 if we could. 02:49:28

MR. NORTH: Your Honor, at this time we would like to display 7933.10 as a demonstrative exhibit. 02:49:38

MR. O'CONNOR: Objection, 803(18).

THE COURT: He's not moving it into evidence. He's using it as a demonstrative to show articles reviewed. 02:49:51

MR. O'CONNOR: But these have statements, summaries from these studies that aren't in evidence, Your Honor.

THE COURT: This does include summaries. Do you agree?

MR. NORTH: Yes, Your Honor. 02:50:10

THE COURT: I'm going to sustain the objection.

BY MR. NORTH:

Q. Let me ask you, do you recall the article by Stein?

A. Yes.

Q. And what did that study basically show? 02:50:16

A. That is basically a retrospective database study of the national inpatient sample which is a big database of hospitalized patients, over 3 million patients, with pulmonary embolism and they showed that basically the patients that received a filter had a lower fatalities rate compared to the patients that did not receive a filter. 02:50:37

MR. O'CONNOR: Objection. That's hearsay, Your Honor.

THE COURT: What's your response on hearsay?

MR. NORTH: My response is, Your Honor, first of all, 02:50:59

I think he's established the requisite for 803(18). But, secondly, under 703, I think he is an expert, can talk about the sorts of data that an expert normally would rely upon even if it is hearsay. 02:51:03

THE COURT: Well, you have to satisfy the last sentence of 703 in order to disclose the evidence to the jury that it was relied upon. 02:51:36

MR. NORTH: May I try to set a foundation, Your Honor.

THE COURT: Yes. 02:51:52

BY MR. NORTH:

Q. Dr. Morris, as a part of your review and reliance or your -- reaching your opinion on the efficacy of filters, do you rely on medical literature that discusses various studies?

A. That's one component, yes. 02:52:08

Q. Do you believe that those studies provide assistance in evaluating your opinion and why you believe filters to be defective?

A. Yes.

Q. What other sources of information do you rely on to reach your conclusions about effectiveness? 02:52:26

A. My personal experience, first and foremost, and then the data presented at national meetings, discussions with colleagues, teaching medical students, residents and fellows all about inferior vena cava filters and -- but primarily I 02:52:50

rely on my personal experience which is pretty extensive. 02:52:58
Q. Well, let me ask you this: In your field of medicine do practitioners generally rely upon medical literature as a significant basis in making determinations as to what will be effective in treating their patients? 02:53:13
A. It's a major component, yes.
MR. NORTH: Your Honor, at this time we would ask that he be permitted to testify.
MR. O'CONNOR: Still going to embrace -- it's still going to involve hearsay, Your Honor. 02:53:29
THE COURT: All right. Come up for a minute if you would, please.
Feel free to stand up.
(At sidebar 2:53.)
THE COURT: Mr. O'Connor, under 703 it can be 02:53:46 hearsay. It can come in. It doesn't need to be admissible to come in under 703.
MR. O'CONNOR: I just saw it.
THE COURT: It says they need not be admissible for the opinion to be admitted and if the facts or data would 02:54:03 otherwise be inadmissible -- so if it's hearsay, for example -- the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.
MR. O'CONNOR: He still has to satisfy 803(18). 02:54:20

THE COURT: No, he doesn't. 02:54:24

MR. O'CONNOR: He can't just come in and summarize an out-of-court statement.

THE COURT: He can under 703. That's what 703 says.

MR. O'CONNOR: I don't read it that way. 02:54:33

THE COURT: The last sentence says: If the facts or data would otherwise be inadmissible, for example, if it's hearsay, it can still be disclosed if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect. 02:54:51

It's well-established that hearsay can come in under that sentence so the question is, do you think that sentence is not satisfied?

MR. O'CONNOR: I don't think that sentence is satisfied because I still think that you cannot overcome or go around this rule that he can come in here and summarize for the jury and now they want to publish his summary statements to the jury. 02:55:01

THE COURT: No. He wants to just ask the questions. He's not talking about publishing it. 02:55:17

MR. O'CONNOR: Okay.

THE COURT: I agreed with you on the publishing.

MR. O'CONNOR: Look it, I understand your point about that rule. It's just that I think at some point we're going to get into a problem with what he wants to tell the jury about 02:55:28

the articles. That's a different story. It's one thing to say, "I reviewed a number of articles. This is the name of the articles and they support my opinion." But it's another thing to go in and start restating what the articles are and publishing them to the jury. 02:55:31 02:55:44

THE COURT: Well, there will be no publishing.

Okay. My ruling based on this exchange is that under the last sentence of 703, the facts and the data, meaning the summaries of the studies, would help the jury evaluate this expert's opinion and I guess I need to hear you explain, Mr. North, if that is satisfied, why that probative value substantially outweighs the prejudicial effect of his sharing this information with the jury. It's the reverse 403. 02:56:02

MR. NORTH: Exactly. First of all, Your Honor, I'm not sure that there is a prejudicial effect. Juries hear all the time and have throughout this trial about learned treatises and the content of articles. That is not a prejudicial sort of thing. So to understand why he reaches the opinion as to the effectiveness of filters, I think it's highly probative for the jury to -- all they have heard about are those two PREPIC articles so far -- to hear about the other articles there. So it's got a great deal of probative value and I am having a hard time in the course of this trial or any trial about scientific evidence seeing how it's prejudicial. 02:56:27 02:56:51

The other point I would make, Your Honor, is I 02:57:06

believe that he has established, or I certainly could establish it if you don't think so with a couple more questions, that each of these articles are learned treatises anyway. 02:57:08

THE COURT: Well, even if you did that, all that would allow you to do is read portions of them or have him do so to the jury. That's not what you're asking me to do. You're asking him to summarize the whole study I believe. 02:57:19

But do you have any argument on the probative value versus the prejudicial effect, Mr. O'Connor?

MR. O'CONNOR: Well, I mean, you pointed out the rule where obviously, I mean, I can't object to that. So I understand your ruling on that. 02:57:37

My concern is when they start trying to publish things and then I'm having to stand up and object at that point. 02:57:54

THE COURT: By publish, do you mean answer questions or do you mean put visuals up?

MR. O'CONNOR: Both. If he starts narrating what these out of court statements say, I don't think that's appropriate. 02:58:04

THE COURT: If you think its inappropriate, by all means, object. But my conclusion is that the probative value in helping the jury evaluate this expert opinion, substantially outweighs the prejudicial effect of summarizing the studies. And so under Rule 703 you can do that, Mr. North. 02:58:17

Subject to any objections you have, Mr. O'Connor. 02:58:21

MR. O'CONNOR: While we're here, just one moment. Earlier you overruled an objection. This report that this expert gave us also included areas where he responded to experts and they never came here to testify. The opinions were 02:58:34 in rebuttal to experts that have not put opinions --

THE COURT: I agree with that. But my conclusion was his opinion was clearly disclosed because he said "my opinion" right here. I think it's the third sentence. "My opinion that Bard retrievable filters are safe and effective," and he 02:58:58 explains it.

So he disclosed that opinion.

MR. O'CONNOR: I saw that. I'm just concerned about other areas coming in that we didn't have anybody to come in and testify to a point that now he's going to be allowed to 02:59:10 rebut here today.

THE COURT: Well, he certainly shouldn't be saying I disagree with the opinion of so-and-so if so-and-so hasn't testified. I agree with you.

MR. O'CONNOR: But if it hadn't come into issue, it 02:59:20 doesn't seem to me it would be relevant.

THE COURT: Well, but this opinion was disclosed. That's my point.

MR. O'CONNOR: I reread it. I understood your point on that. But I am concerned about other areas. 02:59:33

THE COURT: Object if they come up. 02:59:35

MR. O'CONNOR: All right.

(End of sidebar discussion.)

THE COURT: Thank you, ladies and gentlemen.

BY MR. NORTH: 02:59:54

Q. Why don't you just tell us briefly, Dr. Morris, what some of the other studies are that you relied upon in forming your opinion regarding the effectiveness of filters in preventing pulmonary embolism?

A. Well, these studies are essentially retrospective database 03:00:09
studies. Dr. Stein has performed a number of these over the years but the earlier one that I relied upon is Dr. Greenfield's studies from 1997 where he looked at in-hospital deaths in a large patient sample and found that the patients that did not receive a filter had a 44 percent death 03:00:37
rate and those that did receive a filter had an 18 percent death rate.

Another one was published in 2010 by Spencer and that group found that the three-year PE rate with patients that had a filter was only 1.7 percent whereas those that didn't receive 03:01:00
a filter was 5.3 percent. There are lots of others similar studies that basically all show that filters have either a lower PE rate compared to patients without filters or they have a lower case fatality rates than patients that did not receive a filter. 03:01:23

Q. Now, you have told us that another basis of your opinion is your personal experience with filters. How has that impacted your opinion regarding the effectiveness of filters? 03:01:24

A. Well, as of this year, you know, going back to 1991 when I started at University of Vermont, we placed around 2000 filters just in general and I cannot remember any case of a PE-related death after placing an IVC filter. 03:01:45

MR. O'CONNOR: Objection, Your Honor. This has not been disclosed.

THE COURT: Is that in his report, Mr. North? 03:02:06

MR. NORTH: Your Honor, I believe it is.

Your Honor, not that specific instance but he talks about the filters in his practice being successful.

THE COURT: Can I see that, please.

MR. NORTH: I'm sorry? 03:03:07

THE COURT: Could I see that, please.

MR. NORTH: About the fourth line down. Again, in the second paragraph under Dr. Vogelzang, about the fourth line down he mentioned our experience.

MR. O'CONNOR: What page? 03:03:27

THE COURT: Page 21.

I'm going to sustain the objection. The facts that you just shared are not in the report so the jury should disregard the last answer.

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BY MR. NORTH: 03:03:59

Q. Doctor, out of the 2000 or so filters that your group has implanted, can you tell us approximately how many you have implanted?

A. I estimate that I've implanted -- throughout my career, 03:04:09
I've implanted about 800 IVC filters.

Q. Let's talk about some of the filters that you've implanted over the years. What was the first filter that you implanted?

A. The Greenfield filter.

Q. Well, what was the original predecessor on the market 03:04:28
before the Greenfield?

A. It was called the Mobin-Uddin Umbrella. They didn't even really refer to it as a filter at that time. But it was basically developed in 1967 and it was available for use in 1970. It was a surgically placed device that functioned just 03:04:43
like modern day filters except that it had a pretty high complication rate, more than a 50 percent IVC thrombosis or occlusion rate.

So it was eventually displaced by the Greenfield filter which was a new concept, a new design, a conical filter 03:05:04
that would -- I'm sorry.

Q. I'm sorry. If I could, could we display 7933.0004. Was the Mobin-Uddin -- how do you say that?

A. Uddin.

Q. -- Uddin Umbrella the first filter of which you were 03:05:29

familiar? 03:05:31
A. I was familiar with it but by the time I started into radiology, it was replaced by the Greenfield filter. Dr. Mobin-Uddin was a surgeon at Ohio State and -- although he developed the filter I think at Florida when he was there. But 03:05:46
we saw a lot of patients that had the Mobin-Uddin filter in place. And so we did imaging on those patients as well as other types of procedures on them because there were a large number of those at Ohio State when I was a resident there.
MR. NORTH: Your Honor, at this time we would like to 03:06:05
display as a demonstrative 7933.4.
MR. O'CONNOR: Objection. Irrelevant and these photographs are nowhere in his report or a discussion about these photographs.
MR. NORTH: Your Honor, the photograph. 03:06:21
THE COURT: Is the illustration in the report?
MR. NORTH: The illustration is not. There's a long narrative discussion of all of these filters.
THE COURT: Objection is sustained on displaying it.
BY MR. NORTH: 03:06:39
Q. Tell us about the Greenfield filter.
A. So the Greenfield filter was the first conical device that was designed to trap, it was designed to counteract the high thrombosis rate of the Mobin-Uddin filter because it would allow a fair amount of clots to fill up the filter in a 03:06:54

longitudinal fashion and then maintain patency of blood flow around that clot because the clot would be extended into the cone part. 03:06:58

And so the outside of the clot was still moving blood. So it was shown to have a much higher IVC patency rate or a much lower thrombosis rate of five percent or less which was a major improvement over the Mobin-Uddin. 03:07:14

Q. Was there a difference in how the Greenfield filter could be implanted versus the Mobin-Uddin?

A. It first started out as a surgically placed filter, meaning the groin access into the vein needed a surgical cut-down because it was a very large delivery device; but interventional radiologists soon developed a percutaneous technique to place this large delivery device directly into the vein without using a scalpel so they would use a needle and guidewire system to get the filter in. 03:07:33 03:07:52

And Ohio State was one of the institutions that developed that technique and they would argue that they were the first and that Brown University sort of stole their idea and published like six months or a year before they did. But they both basically were working on that technique together at the same time. 03:08:05

Q. Did you implant Greenfield filters yourself as a part of your practice?

A. Yes. 03:08:16

Q. And then after the introduction of the Greenfield, were there a number of other permanent filters introduced to the market? 03:08:18

A. There certainly were, yes.

Q. And can you tell us what the they were? 03:08:30

A. The probably the next one was a Cook Bird's Nest Filter which was another totally different design. It was four very long monofilament steel filaments that sort of wrapped up into a ball in the inferior vena cava, looked like a Bird's Nest. That's why they called the Bird's Nest Filter. 03:08:50

The other was the VenaTech which came out of France which was a conical design. And then right around the same time, late eighties, the Simon Nitinol was marketed.

Q. Now, did you ever in your personal practice implant any of those filters? 03:09:05

A. All of them, yes.

Q. And what was the first retrievable filter that you recall being introduced to the market?

A. The Cook Tulip filter.

Q. And when was that introduced? 03:09:20

A. That was used in Europe for quite a while and then it made its way to the United States in -- I want to say the 2001, 2002 time frame.

Q. Were there any limitations on the Cook Tulip filter as far as how long it could remain implanted before being removed? 03:09:35

MR. O'CONNOR: Objection. Nondisclosure. 03:09:41

THE COURT: Okay. I've actually got a copy of the report. Just tell me where it is, Mr. North.

MR. NORTH: Your Honor, page three.

THE COURT: Okay. Can you point me to where it talks about how long the Cook could be implanted? 03:10:00

MR. NORTH: I'm sorry, Your Honor. I'm not seeing a reference -- and I apologize -- to the specific Cook Tulip filter. There's virtually every other one. Woah. Woah. Woah. At the bottom paragraph. 03:10:13

THE COURT: The objection is overruled based on the paragraph at the bottom of page three.

MR. NORTH: Thank you, Your Honor.

BY MR. NORTH:

Q. So what were the limitations on the implant of the Cook Tulip filter? 03:10:36

A. The Cook Tulip filter was a good filter but we believed, as well as all of the interventional radiologists in the country, that it could only stay in place for anywhere between 14 days and 21 days. 03:10:51

MR. O'CONNOR: Excuse me, Your Honor. I object to this witness testifying what every interventional radiologist in the country thought. Lack of foundation and hearsay.

THE COURT: Overruled.

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BY MR. NORTH: 03:11:04

Q. You may continue.

A. It was common practice to leave it in place 14 to 21 days if it was to be used as a retrievable filter and then we had to make a decision whether we were going to take that filter out 03:11:15 after 14 or 21 days. Most of these patients were not in any condition to have their filter retrieved at that time, so we would have to repeatedly do repositioning procedures which would basically mean we would have to essentially remove the filter but not actually take it out of the patient, move it up 03:11:32 a centimeter or down a centimeter and redeploy it to form a new attachment site. And then that cycle would continue repeatedly sometimes up to six months, so we would to bring these patients down, expose them to radiation, perform angiography, inferior vena cavography, which is x-ray exposure, and do an invasive 03:11:51 procedure under sedation multiple time.

Some of these trauma patients needed their filters in for quite a long time during their convalescence period. So it became very onerous and, quite frankly, dangerous to keep doing that to these patients. 03:12:09

Q. And was it soon after that the Recovery filter for Bard was introduced to the market?

A. Yes, it was.

Q. And did you implant the Recovery filter?

A. Yes, we did. 03:12:20

Q. And what was the reaction among the interventional radiology community to the introduction of the Recovery filter and then soon afterward other retrievable filters? 03:12:21

A. Very favorable, at least for the Recovery filter. It was introduced right around the same time as the OptEase filter, which was also a retrievable filter, and the Recovery filter was unique in that it was shown to be able to remain in place for much longer periods of time. We believed initially up to six months and soon after reports were coming out that it could be retrieved after a year or longer and so that filter did not need those repositioning procedures performed on it before it could be removed. 03:12:37 03:12:56

Q. Are you familiar with the Bard G2 filter?

A. Yes.

Q. Is the Bard G2 filter a filter that can be retrieved? 03:13:38

A. It can be retrieved, yes.

Q. Did you use the G2 filter in your personal practice?

A. Yes.

Q. Can you estimate how many G2 filters you placed over the years? 03:13:55

A. Personally, I placed somewhere between 100 and 200 G2 filters. It was of all the Bard retrievable filters, it was -- it was the one that we placed more of than any other iterations.

MR. NORTH: If we could bring up 7833, please. 03:14:14

BY MR. NORTH: 03:14:22
Q. Do you recognize this photograph, Doctor?
A. Yes.
Q. And what is this?
A. This is a Bard Georgia filter? 03:14:25
Q. And --
MR. NORTH: Your Honor, at this time could we display this to the jury as a demonstrative exhibit?
THE COURT: Any objection?
MR. O'CONNOR: No objection. 03:14:36
THE COURT: You may.
BY MR. NORTH:
Q. Doctor, would you briefly explain to the jury how the G2 filter works?
A. Certainly. 03:14:45
THE WITNESS: May I use a laser pointer on the wall over there?
THE COURT: Yes.
THE WITNESS: If it works.
THE COURT: If it burns the wall, you have to -- 03:14:52
THE WITNESS: So this first version of the G2 filter had what's called a nose cone. I'm sorry, it had a nose and off the nose were six arms. These are the short ones and there were also six legs and this is known as a two-tier filtration device or conical filter. 03:15:17

So that a clot would meet that came out of the leg veins, an embolus would meet two lawyers of filtration. If it by any chance got through the leg cone, it would still have to get through the arm cone up here where it wouldn't continue on to the lungs and cause a pulmonary embolism. So just like its predecessor, the Simon Nitinol filter, it was a two-tiered or dual layer conical filter and that's how it worked. 03:15:20 03:15:37

BY MR. NORTH:

Q. Are there advantages from your view as an interventional radiologist to the two-tier filtering approach of the G2 filter? 03:15:55

A. I believe so, yes.

Q. And what are those?

A. Well, I think there's two chances for the filter to catch the clot not just one chance. 03:16:06

Q. And how does that differ from the Greenfield filter?

A. The Greenfield filter was only a one-tier filter. If a clot passed through the six legs of that Greenfield filter, there was nothing else stopping it. It would continue on sailing to the lungs and causing a pulmonary embolism. 03:16:27

Q. Can you briefly describe how the G2 filter is implanted into a patient?

A. Certainly. We can use either the neck or the jugular vein approach or the femoral vein or the groin approach. The patient is usually sedated although sometimes we do it without 03:16:44

sedation and it's often an outpatient procedure and we stick a needle into the vein using ultrasound guidance. Through that needle -- it's called a Seldinger technique -- we advance a wire into the inferior vena cava, which is the big vein in the abdomen, over that wire. Then we can take the needle out and then slide in a catheter, which is like a pigtail catheter with multiple side holes, and we can advance that into the lower inferior vena cava and then take what's called an inferior vena cava gram picture by injecting x-ray dye or the contrast media, iodinated, which allows the x-rays to show up the lumen of the inferior vena cava. 03:16:47 03:17:02 03:17:18

The main reason we're doing that is to look at the diameter of the inferior vena cava, make sure it's the right size and also to localize the level of the renal veins because the ideal position of the filter is to deploy it just below the level of the renal veins. 03:17:31

Once we have localized those, we can use that as a roadmap image. And then over that same wire, we push it back in through the catheter, remove that catheter and then slide up the introducer sheath. And I'm describing this from a groin approach but it's just reverse from the neck approach. 03:17:47

The introducer sheath is a larger tube that will allow then the IVC filter, which is constrained, elongated and very narrowed and calibered, to be pushed through that sheath. We put that nose that we're seeing, that the leading edge of 03:18:07

that filter just below the level of the renal veins and then slowly uncover the filter by pulling the sheath back and that allows those legs and the arms to spring out and attach to the wall of the inferior vena cava and stabilize it in position at that point. 03:18:12 03:18:31

Q. And in your practice, how long does this procedure generally take?

A. It can take me as little as eight to ten minutes or, in challenging anatomy, it can be 30 to even 60 minutes but I'm average anywhere from about ten to 20 minutes. 03:18:45

Q. Is the patient sedated?

A. Usually sedated yes. Usually sedated although we have done them with just local lidocaine anesthesia.

Q. If the only procedure a patient is having that day is a placement of inferior vena cava filter, is it usually necessary to be hospitalized that night? 03:19:03

A. No.

Q. When the G2 was first cleared by the FDA -- do you recall that?

A. Yes. 03:19:18

Q. -- what was the indication that it was cleared for initially?

A. As a permanent filter.

Q. Even though it was cleared only as a permanent filter, did interventional radiologists use it as a retrievable filter? 03:19:26

A. Routinely, yes. 03:19:30

Q. If a doctor implanted the G2 filter when it was only cleared for permanent use but with the intention of retrieving it later, would that have been an acceptable medical practice?

MR. O'CONNOR: Objection. Nondisclosure. 03:19:46

THE COURT: Can you show me where that is, Mr. North?

MR. NORTH: Yes, Your Honor.

I'm sorry, Your Honor. I can't find it right now.

THE COURT: All right. The objection is sustained.

BY MR. NORTH: 03:20:25

Q. Doctor, I wanted to discuss the removal of a retrievable inferior vena cava. When should a doctor generally consider removing one?

A. When continued IVC filtration is no longer indicated?

And that often is the same time when the patient can 03:20:40 be placed back or onto anticoagulation for the first time.

Q. And what factors do doctors consider when deciding whether to remove an inferior vena cava filter?

A. Well, whether or not they can be treated with anticoagulation or whether the duration of treatment has 03:20:58 expired. And by that I mean most doctors will treat a DVT or a pulmonary embolism for three months, sometimes up to six months with anticoagulation and then stop anticoagulation because they believe at that point the clot has stabilized.

And so if the patient has an ongoing contraindication 03:21:19

to anticoagulation and that three-month period or six-month period as expired, then many doctors will say it's time to remove that filter. 03:21:22

Q. What are the main reasons for not retrieving an inferior vena cava filter? 03:21:45

A. There are multifold. One of the more common reasons cited in the literature is the indication for permanent filtration which I don't necessarily agree with because I think the indications for permanent IVC filters in this day and age are very small. But some doctors still believe there is a -- 03:22:01

MR. O'CONNOR: This opinion hadn't been disclosed.

MR. NORTH: Your Honor, page six, paragraph one.

MR. O'CONNOR: Your Honor, objection, irrelevant. If you look at the title of that section, it's not an issue in this case. 03:22:44

THE COURT: Well, the question is whether this answer was disclosed, not whether the title in the report is relevant.

The paragraph you referred me to, Mr. North, is about when they should be removed. The question is about when they should not be removed. 03:23:19

MR. NORTH: Turning back over to page five at the bottom of the page mentioning ongoing indications.

THE COURT: But it doesn't describe anything you've called for.

MR. NORTH: And then in the middle of the first 03:23:56

paragraph on page six where it says: The initial decision on whether or not to remove an IVCF is individualized and made solely on clinical parameters. 03:23:57

THE COURT: That still doesn't describe the kinds of information called for by your question which are what are the various reason for not disclosing it, so I'm going to sustain the objection. 03:24:09

MR. NORTH: Thank you, Your Honor.

BY MR. NORTH:

Q. Doctor, have you at your hospital instituted a program for patients with retrievable IVC filters? 03:24:23

MR. O'CONNOR: Objection. Irrelevant.

THE COURT: Overruled.

THE WITNESS: Yes, we have.

BY MR. NORTH: 03:24:34

Q. And what sort of program is that?

A. We since 2006 have begun a multidisciplinary IVC filter follow-up program that is performed in collaboration with our hematology experts who are world-renowned thrombosis experts in addition to our trauma surgeons because they used to place some filters. They don't really now but they started that program with us. And then of course interventional radiology and we -- that was the basis of the paper that we published last year, our five-year experience early on with that filter follow-up program. 03:24:54 03:25:15

Q. Have you seen over the course of your career an evolution in the approaches that the community of interventional radiologists take with regard to monitoring of patients? 03:25:16

A. Yes. Early on a lot of patients were lost to follow-up. That was another reason why we weren't removing many of these filters. That was, again, multi-- the reasons were multifold. Interventional radiology trauma surgery, the implanters were often not very diligent in getting these patients back to clinics to follow them up including the primary care physicians as well. 03:25:36 03:26:00

MR. O'CONNOR: Well, Your Honor, this line of testimony is irrelevant because this is not an issue in this case.

THE COURT: Overruled.

THE WITNESS: And -- you are losing my train of thought a little bit. 03:26:10

BY MR. NORTH:

Q. Let me ask. Let's change gears a little bit. We've talked lot about your opinions on benefits of filters. Let's talk some about the risks of complications. Are there risks or complications associated with all IVC filters? 03:26:21

A. Yes.

Q. In the course of your practice, have you ever seen a perfect filter that had no complications?

A. No, because it doesn't exist. 03:26:34

Q. Have you used virtually all the filters on the market over the years? 03:26:38

A. Not all of them. The notable filters I've not used is the ALN and the Option filter. Most of the others I have used, yes. 03:26:48

Q. Do the complications you have seen that you've also seen reported in the literature occur with both permanent and retrievable filters?

A. Yes.

Q. Is it difficult to compare the complication rates in your opinion between permanent and retrievable filters? 03:27:05

A. Yes, very difficult.

Q. Why is that?

A. Well, because a head-to-head trial, a randomized controlled trial, would be very difficult to perform. Not impossible but it has never been performed, to my knowledge. There's an ongoing prospective registry called the Preserve Trial that is going on but a head-to-head randomized controlled trial is very expensive, time-intensive and difficult to perform. 03:27:18 03:27:41

Q. In your clinical practice, have you ever implanted a Simon Nitinol filter?

A. Yes.

Q. And what was your experience with that filter?

A. We thought it had a role but it was not our favorite 03:27:51

filter. We thought it had a fair amount of complications associated with it. The one reason we did like it is because it was very low profile. We could place it through an arm vein. It was that small so patients that didn't have any access -- say both their femoral veins may have been clotted off so we couldn't go from a groin access and maybe their -- they had central lines in their jugular veins so we couldn't use that as an access. So we could place it in through an arm vein but it was fraught with some problems. 03:27:54 03:28:06

Q. What sort of complications did you see in your practice with a Simon Nitinol filter? 03:28:23

MR. O'CONNOR: Nondisclosure, Your Honor.

THE COURT: Where is this, Mr. North?

MR. NORTH: Your Honor, let me get you a copy of the deposition. Beginning at the bottom of page 150 going through 153 he is asked his opinions and experience. 03:28:33

THE COURT: The objection is overruled. What he's just testified to is covered in the deposition.

BY MR. NORTH:

Q. I believe my question, Dr. Morris, was what sort of complications did you see with the Simon Nitinol filter in your practice? 03:29:47

A. Well, the biggest complication we saw was that the Simon Nitinol filter had a tendency to deform itself so it might be the equivalent of tilt in a conical type filter. The daisy -- 03:30:00

I don't know if everyone knows what the Simon Nitinol filter looks like but it has -- it's a two-level filter also with a daisy wheel up on top made of loops of Nitinol material and below that is a conical filter. That daisy wheel would tend to involute or deform and turn in on itself and cause basically a metallic obstruction of the IVC. And we found that there were quite a few IVC thromboses and occlusions with that filter as did some studies in the literature. We also saw quite a few perforations of the leg, I mean, major perforations, Grade 3 perforations of the struts of the filter. So it was not our favorite filter. 03:30:07 03:30:26 03:30:53

Q. What is an occlusion of the IVC or thrombosis of the IVC?

A. That is when the -- then when clot is formed or blocks up the IVC and impedes blood flow so blood cannot return to the heart from the leg veins and that may or may not be a major problem for the patients. Some patients never even know that happens but many of them are symptomatic from that. They develop leg swelling. Sometimes it can be life-threatening. It's called phlegmasia cerulea dolens is the name for the life-threatening term for that. But it can be a major problem and certainly a source of long-term morbidity and misery for the patient. 03:31:15 03:31:37

Q. Are you aware of medical literature that has examined these complications with the Simon Nitinol filter?

A. Yes. 03:31:56

MR. NORTH: If we could bring up 7226, please. 03:31:57

BY MR. NORTH:

Q. And if you could identify for the record what this is.

A. This is a study first author named Poletti which is termed "The Long-term Results of the Simon Nitinol Inferior Vena Cava Filter." 03:32:12

Q. And where was this study published?

A. This was published I believe in "Cardiovascular Radiology" which is the big interventional radiology journal of Europe equivalent to our journal called the JVIR. 03:32:28

Q. Are you familiar with that journal?

A. Yes.

Q. Do you consider it a reliable source for medical discussion and articles?

A. Yes. I have published in it myself. 03:32:37

Q. Is it a peer-reviewed journal?

A. Yes.

Q. What was your understanding of the basic design of the Poletti study?

A. It was a prospective study. They looked at 114 patients that received the Simon Nitinol filter. Many of those patients during their study period died because filters are placed into very sick patients. They ended up with only 38 patients that they investigated and they investigated those 38 patients at almost a three-month -- a three-year time frame so it was 03:32:57 03:33:18

almost a three-year follow-up. 03:33:22

Q. What's unusual about that, a three-year follow-up?

A. A lot of IVC filter studies do not have direct image investigation of complications of the filter longer than six months to a year. So that's somewhat unusual. 03:33:37

And these 38 patients all received a battery of imaging tests, including an ultrasound called a duplex ultrasound, that looked at whether or not the inferior vena cava IVC was open or clotted off. They also received an abdominal x-ray and that looked for fractures and other types 03:33:55 of complications, what they called eccentric positioning. And then the third set they all received was a CAT scan so they compiled all the complication data of those 38 patients based on those three studies.

MR. NORTH: If we could turn to page 291 of the 03:34:16 article, Table 2.

BY MR. NORTH:

Q. Did the authors report their findings regarding complications with the Simon Nitinol filter?

A. Yes, they did. 03:34:46

Q. And what number of patients or percentage of the patients did they find IVC perforation in?

A. 95 percent.

THE COURT: Hold on just a minute.

MR. O'CONNOR: Objection. Hearsay, Your Honor. 03:34:57

THE COURT: Overruled under 803(18). 03:34:59

THE WITNESS: 95 percent and 76 percent of those have what we called Grade 3 perforations meaning the perforated strut was interacting with a structure outside the inferior vena cava. 03:35:14

BY MR. NORTH:

Q. And how many -- what total percentage of the Simon Nitinol filters were perforating?

A. 95 percent.

Q. What percentage of the Simon Nitinol filter in this particular study had evidence of strut fracture? 03:35:26

A. 16 percent and that is of the legs, not the daisy wheels, so 16 percent were fractured legs of the Simon Nitinol filter which those are the dangerous types of fractures because those may or may not be stable. But the daisy wheel fracture is -- because it's a loop, it's still attached to the filter so it's not going to embolize; but if the leg fractures, it can embolize. 03:35:49

Q. Of the 38 patients that were examined, however, with these complications, did these patients have symptoms with these perforations or fractures? 03:36:07

A. Remarkably they did not have symptoms.

Q. We've talked about known risks. Is perforation or penetration into other organs a known risk of all inferior vena cava filters? 03:36:37

A. Yes. 03:36:39

Q. And is tilt a known risk of all filters?

A. Yes. Well, I should say all conical filters. Some filters are designed so they are really difficult to tilt. For instance, the TRAPEASE and the OptEase, because of their unique 03:36:53 design, they really can't tilt although I have seen them somehow end up sideways. That's a very, very rare event in the vena cava.

Q. Were perforation, tilt, migration, and fracture all known risks in the interventional radiology community in June of 03:37:10 2007?

A. Yes.

Q. And as a part of your practice over the years, have you kept abreast of the medical literature and studies related to IVC filters? 03:37:21

A. Yes.

Q. And have you seen these various risks associated with the filters discussed and reflected in the medical literature over the years?

A. Yes. 03:37:36

Q. Over the years have you discussed these risks associated with IVC filters with your interventional radiology colleagues?

A. At various times and at various venues. We have periodic sessions called journal clubs, where we review and critically analyze studies and we have other types of small groups, 03:37:59

regional groups called angio clubs where we discuss these issues and at national meetings and venues such as those. 03:38:04

Q. Doctor, let's turn now to your fourth opinion concerning the G2 filter specifically. In your personal practice, what was your experience with regard to the G2 filter? 03:38:27

A. It was very favorable.

Q. Did you experience any complications with the G2 filter as a part of your practice?

A. We may have seen a few fractures but -- and certainly some perforations. All filters seem to perforate. Bards are no exception as far as perforations. But we did not see any symptomatic perforations and although we did see a few struts, Grade 3 type perforations, they seemed to be -- we were lucky to not have symptoms associated with those. So, yes. 03:38:45

Q. Can you estimate how many Bard's G2 filters your group has removed over the years? 03:39:09

A. Removed. It was our most popular filter and this would just be a guess. I would say that we probably removed somewhere between 100 and 200 G2 Filters.

Q. And do you recall how many instances where the IVC had fractured, IVC filter had fractured that you noticed during the retrieval? 03:39:31

MR. O'CONNOR: Objection, nondisclosure.

THE COURT: Where is that in the report?

MR. NORTH: Your Honor, page 21, fourth line from the 03:39:44

bottom to the page 22, second line. 03:39:46

MR. O'CONNOR: I'll withdraw the objection, Your Honor.

THE COURT: All right.

BY MR. NORTH: 03:40:23

Q. I believe the question was, what you had seen, how many instances of fracture you had seen with G2 filters in the course of your group's practice?

A. I can't address the G2 specifically although that was our most popular filter of all the G2 retrievable filters. But out 03:40:35 of the 800 or so that we have placed, we have seen maybe seven or eight fractures and that is an increased number since we -- I wrote that expert report where I said maybe four or so because I dove into my teaching files very deeply to find a couple others and we had another couple since I wrote that 03:41:02 report.

Now, some of those, at least two of those fractures we don't know whether they preexisted or they occurred during the retrieval process because at least one of my cases and another one of my partner's cases, our fellow that was doing 03:41:22 the procedure did not get an image before he manipulated a catheter through the filter so it's possible that his catheter manipulation fractured the filter. But in both cases we removed the entire filter and the fractured segment at the same time. So that's why I say I don't know if it was up to seven 03:41:41

or eight. It could have been as low as six. 03:41:46

Q. Were any of those instances of fracture symptomatic with the patients?

A. We have had several that have fractured struts that had embolized to the heart and/or lungs and they have been 03:42:01 symptomatic in the sense that at some point they ended up in the emergency room with chest pain; but we don't know yet whether that chest pain occurred after they knew that they had a fractured filter or not. Neither of those were deemed to be indicated for retrieval by our cardiovascular surgeons because 03:42:22 they did not think they were truly symptomatic in those patients.

Q. What is your understanding of what instructions for use are?

A. Any medical device has a document called the instructions 03:42:36 for use associated with it in the delivery box that arrives with the device. And that document helps the operator understand indications, contraindications of use of that device as well as proper and recommended deployment procedures as well as some of the -- some of the complications that can be 03:43:03 expected, potential use of that device. So it's sort of a general information document related to the device for the operator.

Q. When you used the G2 filter with your patients, did the filter come with an IFU? 03:43:23

A. Each and every one, yes. 03:43:25
Q. And did you read the instructions that accompanied the G2 filter?
A. I did initially, yes.
Q. As part of your medical practice, do you customarily read 03:43:35
the instruction manuals or instructions for use that accompany all the medical devices that you utilize?
A. Not every -- well, after placing, you know, several hundred, we stop reading it. So I'll read it once or twice
early on if it's a new device that we have never used, for 03:43:52
instance, but it gets repetitious after a while so we don't continue to read them, no.
MR. NORTH: If we could bring up Exhibit 994.
And, Your Honor, I believe this has been admitted.
COURTROOM DEPUTY: Yes. 03:44:35
THE COURT: It has been admitted.
MR. NORTH: Could we display it to the jury, Your Honor?
MR. O'CONNOR: But this isn't mentioned in his
report, this IFU. 03:44:40
THE COURT: Is this mentioned in the report, Mr. North?
MR. NORTH: Pages 10 -- just a second, Your Honor. Let me find the exact portion on page 10, Your Honor.
Beginning on page 10, carrying over to 11 he lists all of the 03:45:10

complications of -- all of the stuff on the Denali IFU and then at the sentence on the bottom of page 11 starting "interestingly" confirms that the same language was in the G2. 03:45:14

THE COURT: But do you identify the IFU as an exhibit to be used during his testimony, the G2 IFU? 03:45:39

MR. NORTH: Your Honor, I'm sorry. I don't have the reliance list here with me to be able to say. I mean, we gave them notice yesterday that this was an exhibit.

THE COURT: Well, under Rule 26 you need to identify the exhibits to be used by the expert in the report. Was that done for the IFU? 03:45:59

MR. NORTH: Your Honor, we don't have that list with us so I'll just move on.

THE COURT: All right.

BY MR. NORTH: 03:46:26

Q. Doctor, have you generally read the warnings in the G2 --

A. Yes, I have.

Q. -- IFU?

Do you believe that those warnings about risk of movement, fracture, and perforation afford fair and adequate notice of the possible consequences of using the G2 filter? 03:46:42

A. They are well described, yes.

Q. Doctor, do you have an opinion as to whether the G2 filter tilts, migrates, perforates, or fractures more than other filters that were available while the G2 was on the market? 03:47:04

MR. O'CONNOR: Objection, Your Honor. This was not disclosed. 03:47:08

THE COURT: Mr. North?

MR. NORTH: Beginning on page 21, fourth line from the bottom, talks about the complications and his experience with the Bard filters. 03:47:24

THE COURT: There's no comparison to other filters?

MR. NORTH: Not specifically.

THE COURT: Objection sustained.

BY MR. NORTH: 03:48:05

Q. Did you review generally the medical literature concerning the G2 filter?

A. Yes.

Q. And what did that literature indicate to you over all regarding the filter? 03:48:15

A. There are studies, some studies that have stated and found based on their methodology, that the G2 filter had some high complication rates and then there are studies that have shown low complication rates of the G2 filter.

Q. And in your personal experience, were the complication rates associated with the G2 low, medium or high? 03:48:39

A. We found them to be low.

MR. NORTH: Thank you, Doctor. That's all I have.

THE COURT: Cross-examination?

CROSS - EXAMINATION

BY MR. O'CONNOR:

Q. Dr. Morris, hi. My name is Mark O'Connor. This is the first time we've met.

Let me ask you a question. You haven't received internal documents from Bard, have you? 03:49:52

A. No.

Q. And so what Bard's -- the medical director at Bard, his opinion regarding the Simon Nitinol filter you just don't know, do you? 03:50:05

A. No.

Q. If he has come out and stated in a document that the Simon Nitinol filter had virtually no complaints, you have no way to address that because you did not see the document or talk to the medical director at Bard. Fair? 03:50:20

A. I did not, no.

Q. Thank you.

And when you talk about studies, I thought I saw something on page eight of your report. Let me ask you this: There are no randomized control studies showing the efficacy of IVC filters in preventing recurrent or acute pulmonary embolism compared to no treatment in patients without a filter. Is that true? 03:50:42

A. That's true, yes.

Q. And basically, that is the conclusion from PREPIC 2? 03:50:56

A. No. Because both PREPIC studies -- no. They did not because all those patients were treated. 03:51:01

Q. I understand the distinction. But basically to your point, if -- there's been no study comparing filter -- if filters will prevent PE compared to patients that did not have a filter. Was that your point before? 03:51:16

A. Yes correct.

Q. Thank you.

Now the Simon Nitinol filter was the predicate device that to the Recovery; correct? 03:51:41

A. Correct.

Q. But you don't know -- in terms of comparing the Recovery versus the Simon Nitinol filter regarding failures, you haven't seen anything to that extent?

A. There's been no direct comparison between the two. 03:51:54

Q. What you do know from reading the literature is that the Recovery filter had been failing in terms of migrating, perforating, tilting and injuring patients; correct?

A. All filters --

Q. I'm just asking about the Recovery. 03:52:07

A. There are some studies that show complications with the Recovery, yes.

Q. And just staying on the Recovery. You're aware that patients were -- there were deaths associated with the Recovery filter, too; correct? 03:52:19

A. Yeah. I know about the reported migrations of the entire filter into the heart that caused some deaths, yes. 03:52:20

Q. All right. And also as you said, there is literature talking about the complications of the G2; correct?

A. Yes. 03:52:34

Q. Now, you have not reviewed Sheri Booker's's medical records, have you?

A. No.

Q. You weren't asked to look at her records; fair?

A. No, correct. 03:52:44

Q. And I went and looked through your reliance list. You never look at the IFU that applied to her case in preparing your report?

A. Oh, not in preparing the report. I have read that IFU, yes. 03:52:54

Q. You know that her filter -- she received her filter when it was cleared to be permanent only?

A. I don't even know that.

Q. So you have no reason to dispute that statement?

A. No. 03:53:07

Q. You stay apprised of the literature, do you?

A. I try to, yes.

Q. And you agree that the knowledge among the medical community began to become more prevalent about fractures including fractures of the G2 and the Recovery, around 2010; 03:53:52

right? 03:53:56
A. Well before that.
Q. Well, 2010 is when a communication came out from the FDA; true?
A. Right. Right. Correct. 03:54:04
Q. And there's been medical literature that has been written about the timing when there was more and more increasing awareness of filter failures; correct?
A. Yes.
Q. And you told us that you had been a consultant with Bard 03:54:21 going years back; right?
A. Yes.
Q. And it was -- was that for filters?
A. Yes.
Q. And so you have been involved with Bard for how long? 03:54:32
A. I want to estimate probably between maybe 2003 and 2006, something like that, and it wasn't just filters. I was involved in a focus group about stents and stent graphs and other products as well.
Q. That's right. I recall you saying that. 03:54:51
Now, one thing it would seem to me, Dr. Morris, that you would agree with, that a medical device company like Bard has to put patient safety first and foremost; correct?
A. Yes.
Q. And certainly they do have to communicate accurate and 03:55:03

truthful information to members of the medical community like yourself; true? I mean, you rely on their information to a certain extent anyway; correct? 03:55:08

A. To a certain extent? That's not my primary source of medical information, the company, no. 03:55:21

Q. When you talk about fractures being asymptomatic, what you're talking about, a patient not necessarily having symptoms that he or she can perceive or relate to a physician; correct?

A. So a symptom is a subjective parameter, so the patient has to report a symptom, yes. 03:55:45

Q. Certainly you agree that a filter can fracture and be in a location that may be dangerous to a patient and the patient not have any symptoms?

A. Yes.

Q. And that is a danger of a filter fracture; true? 03:55:56

A. None of us would want a filter fracture, correct.

Q. A filter can break and migrate and a patient may never know until it's too late; right?

A. By "too late," you mean develop a symptom?

Q. Well, a patient may have a filter fracture and not have any symptoms and finally when symptoms evolve, find out or learn that that fragment migrated to her heart and that would be dangerous correct? 03:56:16

A. That could be potentially, yes. Rarely, yes.

Q. And so I don't think -- you're not here to tell the jury 03:56:34

that a fracture that is not causing symptoms, you're not saying that's not a serious condition, are you? 03:56:36

A. It's not a serious condition but I believe it's rare for that to cause a symptom and become a life-threatening situation. 03:56:51

Q. But there have been no studies on filter fragments and the length that they will remain asymptomatic. Is that true?

A. That's true, yes.

Q. And what you and other members of the medical community are becoming more and more aware about -- of is that there are filters breaking, including Bard filters, that are leaving fragments in patients and now what you're faced with in the medical community is how to get those fragments out. Fair? 03:57:06

A. Not necessarily. That needs to be determined on an individual basis. For instance, I just testified that our last two patients that we found -- where we found fragments, one in the heart, one in the pulmonary artery, we collectively -- not me personally my partners and the cardiothoracic surgeons -- decided to leave those alone, to not remove them percutaneously or surgically. 03:57:23 03:57:43

Q. But the issue is, you can't ignore them. You need to make a decision about what to do about a fragment; right?

A. Well, to the extent that they are being followed clinically, yes, those patients should continue to be followed, yes. 03:57:55

Q. It's something that you, Dr. Morris, take seriously if you see a fragment anywhere in a patient's body regardless of whether it's causing symptoms or not; correct? 03:57:55

A. Yes, I take that seriously.

Q. Very seriously? True? 03:58:08

A. Yes. Yes.

Q. And you would urge medical device companies to take that seriously as well. Fair?

A. Yes.

Q. Thank you. 03:58:19

MR. O'CONNOR: That's all I have.

Well, let me make sure.

No more questions, Your Honor.

THE COURT: Any redirect?

MR. NORTH: One second, Your Honor. 03:58:39

Nothing further, Your Honor.

THE COURT: All right. Thank you, sir. You can step down.

MR. O'CONNOR: Oh, wait a minute. I do have one more question if I may. 03:58:59

MR. NORTH: And I have one redirect.

THE COURT: Go ahead, Mr. O'Connor.

BY MR. O'CONNOR:

Q. Are you aware of the study that Dr. Trerotola and Dr. Stavropoulos just published in 2017? 03:59:22

A. About fragment retrievals? 03:59:27
Q. Yes.
A. Yes.
Q. And you're aware that they stated in that study that it was 2010 when the medical community became more increasingly 03:59:33
aware of filter fractures, including G2 and Recovery fractures?
A. They stated that, yes.
Q. So it was in that era of 2010 where it really became known to the medical community, according to Trerotola and
Stavropoulos? 03:59:57
A. Yes. Because of the Hall and the VJ studies but we knew about the fractures before they actually published those.
Q. They said that the medical community on a whole --
A. Oh. Okay. Well, I don't know about that.
Q. Well, the IRs, you saw that. And I can put it up there. 04:00:12
MR. O'CONNOR: Do we have it. 7357. And go to page seven.
BY MR. O'CONNOR:
Q. Well, first of all, Doctor, are you familiar with the article that we're showing? And it's Exhibit 7357? 04:00:30
A. Yes. I've read it. Not recently but I've read it.
Q. And I take it that this is literature that you would regard as being authoritative?
A. Yes. It's a good study.
Q. All right. 04:00:43

MR. O'CONNOR: Greg, let's go to page eight. How about page seven, excuse me. I don't have my notes in front of me. And under Discussion, Greg, that sentence, "fracture of optional," do you see that? If you could highlight that and then go up to the top of the next column to continue along the paragraph. 04:00:45 04:01:16

BY MR. O'CONNOR:

Q. Well, let's read this, Doctor. According to Drs. Trerotola and Stavropoulos, fracture of optional IVC filters began to be recognized in the late 2000s. 04:01:32

Did I read that correctly?

A. Yes.

Q. And we're going to have to go up the column. It says: However, large-scale recognition of filter fracture began in 2010 with publication of a filter fracture series by Nicholson and a subsequent United States Food and Drug Administration warning. 04:01:43

Did I read that correctly?

A. Yes.

Q. All right. Thank you. 04:01:56

THE COURT: You must be finished, Mr. O'Connor.

MR. O'CONNOR: I think so.

Well, I guess I have one more question. Excuse me.

BY MR. O'CONNOR:

Q. And in that Stavropoulos-Trerotola study, they talked 04:02:31

about the G2 and the fractures that were occurring in the G2; correct? 04:02:35

A. Yes.

Q. Do you see where I'm looking?

A. Yes. 04:02:47

Q. And G2, according to their study, had the highest number of fractures and fragments retained locally. Do you see that?

A. Oh, yeah.

Q. So the G2 was highest of the filters that they were looking at in terms of fractures and fragments? 04:03:02

A. It was also the filter with the largest N, so they saw more G2s than any other filter. So, I mean, that is one reason why they saw so many G2 filters, because they saw 37 G2 filters. The next most popular filter was the Celect at 20. Remember they are a tertiary care referral center so they are 04:03:30 getting filters from all around the -- filter fragments -- fractured filters from all around the country.

Q. Well, if you look at Table 3, Filter Fragments Embolize to Lungs According to Brand and Element Embolized. Do you see there? 04:03:45

A. Yes.

Q. And G2 had 11. Do you see that?

A. Yes. 11 out of 52.

Q. And then going over, it talks about arms and legs. Do you see that? 04:04:01

A. Yes.
Q. And it talks about ten relating to the embolization to the lungs according to brand and element embolized. Do you see that?
A. Yes. 04:04:17
Q. Do you see that?
A. Yes.
Q. Let's go to Table 5. And Table 5 has to deal with filter fragments embolized to the heart according to brand and element. Do you see that? 04:04:28
A. Yes.
Q. And at the top of that list is the Recovery with six out of 67. Do you see that?
A. Yes.
Q. And then when it talks about the arms and legs going to embolize to the heart, the Recovery had six; correct? 04:04:37
A. Yes.
Q. And then right under that, the next one under that is the G2 with filter fragments embolized to the heart. In Trerotola's study there were two of 22 they found went to the heart and two that related to the arms and legs. Is that fair? 04:04:56
A. Yes.
Q. Thank you.
MR. O'CONNOR: That's all I have I think.
THE COURT: Redirect? 04:05:07

REDIRECT EXAMINATION

BY MR. NORTH:

Q. Doctor, when Mr. O'Connor had you read the parts of that article about widespread recognition of filter structure, that was not specific to Bard filters? 04:05:08 04:05:20

A. No. That was about retrievable filters in general. And the reason my belief -- and this is my opinion -- that the reason that occurred was because these retrievable filters for the first time were being investigated very thoroughly by imaging because we were retrieving them. We never did that with permanent filters. We placed permanent filters and never saw those filters ever again. We may have seen them with random imaging here and there but we were not following them with imaging. 04:05:41

Now we had this big group and this was the largest group of filters ever placed in the history of the world because we were placing these in trauma patients prophylactically and we could take them out after a period of time. So this huge group of filters now we were investigating with fluoroscopy trying to take them out and now we had all of this follow-up on all of these filters. 04:05:54 04:06:10

Now, if you go back and look at imaging, in a lot of these permanent filters, there's quite a few of those that are fractured as well so that's why I am -- I think that the retrievable filters were for the first time investigated very 04:06:25

thoroughly and the permanent filters were not investigated that thoroughly on a widespread basis. 04:06:28

Q. Doctor, do you hold all of the opinions that you have given here today to a reasonable degree of medical certainty?

A. Yes. 04:06:40

Q. Thank you.

MR. NORTH: That's all I have, Your Honor.

THE COURT: Okay. Thank you.

Now you can step down.

(Witness excused.) 04:06:45

MS. HELM: Your Honor, we call Dr. Stavros William Stavropoulos by video.

Dr. Stavropoulos is a medical doctor who is a board certified radiologist with a specialty in interventional radiology. He maintains a clinical practice in interventional 04:07:34 radiology at the Hospital of the University of Pennsylvania and is a professor of surgery and radiology in the medical college there.

He graduated from Loyola University Chicago Stritch School of Medicine and has implanted and retrieved IVC filters 04:07:55 for over 20 years.

(Whereupon the video deposition of Dr. Stavropoulos was played.)

THE COURT: Is that the end of the video?

MR. NORTH: Yes, Your Honor. 04:20:45

THE COURT: All right. Then we'll make that the end of the day as well. 04:20:46

Ladies and gentlemen, we will plan to begin tomorrow morning at 9 o'clock and we'll excuse the jury.

(Jury departs at 4:21.) 04:20:55

THE COURT: All right. Please be seated, or leave if you want to leave.

Counsel, what's the adjustment for today on the deposition time?

MR. NORTH: Where did Ms. Helm go? 04:21:32

MS. HELM: I had it written down, Your Honor. Total of six minutes should be allocated to the plaintiff. A total of six minutes should be allocated to the plaintiff.

THE COURT: Okay.

MS. HELM: For all three -- total for all three videos. 04:21:46

THE COURT: Okay. Give me just a moment.

All right. Counsel, as of the end of today, plaintiff has used 28 hours and 18 minutes and defendants have used 20 hours and 35 minutes. 04:23:44

I think -- actually, I need to grab some papers for jury instructions. Do you all need a break before we talk about those?

MS. HELM: Yes, please.

THE COURT: So we'll take a ten-minute break and 04:24:08

we'll resume at 25 to the hour. 04:24:10

(Recess at 4:24; resumed at 4:34.)

(Court was called to order by the courtroom deputy.)

THE COURT: Go ahead and be seated. Thank you.

Mr. Lopez, come on up for a minute. Let me ask you a question. This may or may not solve the issues that we had today. There were issues that came from the plaintiff wanting to put in the last three pages of 4327 and an argument made at sidebar by you, Mr. Lopez, was that it can be admitted for notice and not for the truth of the matter asserted. 04:36:44 04:37:03

You, Mr. North, wanted to put in the SIR guidelines. There was a hearsay objection and you suggested that that come in for notice, not for the truth of the matter asserted. It seems to me one solution is to admit them both for notice with an instruction that it's not to be considered for the truth of the matter asserted. 04:37:23

I'm not saying you have to agree to that but I thought since you're both making that argument with respect to an exhibit, that might avoid the need for further argument on hearsay within hearsay and other issues. 04:37:36

MR. NORTH: You should take over the Mideast peace talks. I'll go with that.

MR. LOPEZ: We haven't ceded yet, Judge. On the issue of my -- I'll consider that. I will, Judge.

But on the issue of the document that I want to get 04:37:56

in, 4327, I should have it memorized by now. I'm working on the evidence code subsections. I think it actually is non-hearsay, Your Honor, because I understand that some of those where it says reports that doctor says but some of them just says rep reports or marketing manager reports. So there's no -- there's no in between hearsay. 04:37:58 04:38:19

THE COURT: Well, on that, I looked at Weinstein's on evidence over the lunch hour. It contains this statement under 805 which is hearsay within hearsay: The problem of multiple hearsay often arises when a party seeks to introduce a business record and the person who made the record has no personal knowledge of the underlying event and has based the entry on information supplied by another. 04:38:38

It seems to me there's four different categories of evidence in 4327 that fall into that description. One is -- well, some is more explicit. Some says the doctor stated, actually quotes what the doctor said. Others are where it's a report of a rep and the rep is saying the doctor had difficulty manipulating this or finding this or grasping the strut. That information had to have come from the doctor. 04:38:56 04:39:23

A third is actually a different category which is DM. Didn't get any evidence as to who DM is. So there's several different categories I think, all of which fall within this situation of the person being quoted having no personal knowledge and having necessarily gotten it from others. That's 04:39:46

hearsay within hearsay according to Weinstein's under Rule 805. 04:39:50

So, I mean, if you want to argue this more, we won't do it now. I'll be happy to hear from you. But seems that's tough not to conclude that we've got different categories of hearsay within hearsay in Exhibit 2738. 04:40:06

MR. LOPEZ: I looked at some of those. On its face, it does say that the rep reports. I mean, we don't know whether or not the rep had personal knowledge of those events or not.

THE COURT: Exactly. 04:40:23

MR. LOPEZ: But on its face, you can't say he didn't because it says that he's the one who is --

THE COURT: How can we think that the rep knew that the doctor had difficulty managing the deployment, that doctor met resistance? 04:40:38

MR. LOPEZ: He viewed medical records. I'm speculating, Your Honor.

THE COURT: Exactly. I need by a preponderance of the evidence to conclude that this was based on the personal knowledge of the rep if I find the rep was an agent authorized 04:40:51 to speak under 801(d)(2).

MR. LOPEZ: My position on that is if this is something that is done in the regular course of business, it's part of their business practices, that sales reps are supposed to return that type of information they get to the company. 04:41:04

That is still something that is reported by the sales rep. It should not be hearsay. Certainly it's notice. I mean, it's notice to the company. 04:41:07

THE COURT: That's where I started. I think it is hearsay but if you want to use it for notice, do you have an objection to their using the SIR guidelines for notice. 04:41:19

MR. LOPEZ: Can we tell you at 8:30?

THE COURT: Yes. If you don't want to agree to that, then we'll deal with the hearsay within hearsay issue. I thought that might be a way to avoid it. 04:41:34

MR. LOPEZ: I'll say this: It's tempting but I don't want to make a spontaneous decision.

THE COURT: Give it some thought. That's fine.

Okay. Jury instructions. We've handed you a redacted documents instruction. Any concerns about that? We made this up. We didn't get it from some source so feel free to criticize it. 04:41:59

MS. LOURIE: We have no objection.

MS. HELM: Neither do we.

THE COURT: Okay. See we'll include that. 04:42:27

We had left out in the original proposal model instruction 3.5 on return of verdict. Seems to me we need to include that. I don't think there's a problem with that. It's just the standard language.

Is that acceptable to both sides? 04:42:44

MS. LOURIE: Yes. The instruction is fine. 04:42:50

MS. HELM: Same, Your Honor.

THE COURT: Okay. So we'll include that, too.

Now, I think what we ought to do is talk through the instructions that we gave you yesterday with red-line changes 04:43:06
and a clean copy to see where you have concerns and we're still going to take all of these headings off in the final set. So it will just be an instruction number. But working through that set, I do think we -- well, let's stop on 1.8. That's where we combine the parties to Bard and we said you should 04:43:36
decide the case for the two defendants jointly.

Any concerns about that change?

MS. LOURIE: No concerns from us.

MS. HELM: None, Your Honor.

THE COURT: Okay. We still have a question mark on 04:43:54
1.10 that we think we now should remove. I had left it on because I hadn't given any limiting instruction, but we're about to get to one on redacted evidence. So it seems to me that we should just give all of what's in 1.10. And I left the question mark in to see if we should take anything out of 04:44:17
paragraph three. We've excluded some testimony and we're now instructing them as to redacted documents, so it seems to me the whole thing should come in.

Any disagreement?

MS. LOURIE: No, sir. 04:44:30

MS. HELM: No, sir. 04:44:31

THE COURT: 2.14, I can't think of any chart or summary that has been put in evidence as a summary of other evidence like under 1006. Certainly there's been lots of charts in different documents that have come in. I guess the 04:44:56
question is, do you think we need to give 2.14? Oh, I'm sorry. This is it's one for demonstratives. Clearly we need to give the one for demonstratives. I'm talking about 2.15.

MS. LOURIE: I believe we introduced a summary chart of the medical bills into evidence. 04:45:23

THE COURT: And did that come into evidence?

MS. LOURIE: Yes, sir.

THE COURT: Okay. Then we should give 2.15 and 2.14.

MS. HELM: Yes, sir.

THE COURT: Okay. 04:45:35

That takes me up to page 13, strict liability/design defect. Do any of you have concerns about anything before that?

MS. LOURIE: We don't.

MS. HELM: No, sir. 04:46:02

THE COURT: Okay. Any comments on the strict liability/design defect instruction?

MS. LOURIE: Yes, sir. We see that you moved the requested paragraphs and we appreciate that. Our only comment would be that we think you moved it a little bit too low. It 04:46:17

goes below number 13 on page 14. I believe that paragraph immediately below 13 is more like a concluding paragraph that should go to the end of the instruction. 04:46:21

THE COURT: Do you agree, Ms. Helm?

MS. HELM: I do, Your Honor. 04:46:44

THE COURT: So you're talking about the paragraph that begins "If you decide"?

MS. LOURIE: Yes, sir.

THE COURT: Okay. So we'll move that to the end.

Any other comment, Ms. Lourie? 04:46:52

MS. LOURIE: No, sir.

THE COURT: Ms. Helm, do you have other comments on that instruction?

MS. HELM: No, Your Honor.

THE COURT: Okay. How about strict liability, failure to warn? 04:46:59

MS. LOURIE: I don't know if you want me to perfect the record now. We had asked for an added sentence. You did not indicate you were going to add it so just to perfect the record, I don't know if you will want me to address that now. 04:47:16

THE COURT: If you want to put it on the record. I assume you're talking about the first full paragraph on page 17. You wanted to add a sentence after that?

MS. LOURIE: No. We agree with the way you did that one. We agreed to that the other day. It's actually the 04:47:33

second full paragraph that begins with "You must decide," we asked that the sentence, "A warning is inadequate if it does not provide a complete disclosure of both the existence of the risk and the extent of the danger and the severity of any potential injury involved," we asked that that be added to the end of that paragraph and we just want to perfect that. 04:47:36 04:47:52

THE COURT: And remind me, Ms. Lourie, of the source of that.

MS. LOURIE: That is all case law, Your Honor. It's from our plaintiff's request to charge number four. 04:48:11

THE COURT: You're right. Yes, I did look at that. I did conclude not to include it because I thought it was too much of a comment on the evidence, but your objection to that is preserved.

Ms. Helm? 04:48:38

MS. HELM: Yes, Your Honor. We have no issue with the language of the charge but we believe that defendants' request to charge number four relating to failure to read the IFU is warranted by the evidence.

THE COURT: You were going to come up with an alternative I think when we talked before because I made the point when we talked last time that we can't say the jury has to rule for the defendant if the doctor failed to read because the allegation is there were other ways in which the defendants failed to warn the doctor. 04:48:53 04:49:13

MS. HELM: I actually have an alternative, Your Honor, that Mr. North didn't know about and I've given it to the plaintiffs. 04:49:15

THE COURT: Do you have a copy?

MS. HELM: Yes, Your Honor. May I approach? 04:49:22

THE COURT: Yes.

MS. HELM: Your Honor, the failure to read goes to the element of adequacy of the warning, not the ability to communicate the warning or how it was communicated. That's the *Wilson* case specifically says that. So I rewrote it to go to 04:49:52 the element of adequacy of the warning.

THE COURT: So I think what you're suggesting, Ms. Helm, is that if you look at the instruction, the top of page 17 indicates two ways in which the duty to warn can be breached. One is with failing to provide an adequate warning. 04:51:15 The second is by failing to adequately communicate the warning.

MS. HELM: Correct, Your Honor.

THE COURT: And your proposed instruction would say if Dr. D'Ayala did not read the IFU, then the jury should find for the defendants on the first of those two. 04:51:39

MS. HELM: Correct, Your Honor, and that's exactly the *Wilson Foods v. Turner* case which we cite. In that case, the plaintiffs alleged both failure -- both the adequacy of the warning. And failure to adequately communicate the warning and Georgia is a directed verdict state and in that case, the Court 04:51:56

directed a verdict as to the adequacy of the warning but said that failure to adequately communicate the warning went to the jury so they gave a partial directed verdict based on the failure to read the warning. 04:51:59

THE COURT: Was that a case where the plaintiff alleged that there were multiple avenues of warning that should have been pursued? 04:52:12

MS. HELM: Your Honor, actually, the adequacy of the warning cases in Georgia all relate to -- at least all of the ones that I have been able to find or we have been able to find relate to the failure to communicate an adequate warning based on things like the location of the warning, the presentation of the warning, you know, font, color size. The example is you put the warning under the seat of the bike and no one looks under the seat of the bike. 04:52:29 04:52:47

THE COURT: That's the failure to communicate.

MS. HELM: Yes, Your Honor. That's the type of cases that there are. There are some outside of Georgia cases talking about other ways to communicate. But all of the case law in Georgia says if there was a warning and you didn't read the warning or you didn't prove that the warning was read, that breaks the causation for the adequacy of the warning. 04:53:02

So we understand the Court's position that there were other ways to communicate although I don't think there was any -- I don't know that the evidence proves that here in this 04:53:20

case as the experts all testified about the adequacy of the warning. If you look at Dr. Hurst's testimony, it was: Was this in the IFU? Was this in the IFU? Was this in the IFU? But it's an "or" standard; and if they haven't established that the IFU was read, then the first part of the "or" fails. 04:53:24 04:53:43

THE COURT: All right.

MR. STOLLER: Your Honor, I addressed this in two parts. I think first off, it's an inaccurate statement on its face which is a direct verdict in favor of the defendants if we are -- the doctor purportedly did not read the warnings. The testimony here has been that the warnings come in multiple different ways, not just the IFU but through brochures, through sales reps, through all kinds of communicating and Dear Doctor letters and those sort of things. It is not a black and white. It is in the IFU and, therefore, failing to provide it in the IFU is the question under A of those two prongs. The adequate warning is in every way they communicated and failed to communicate to those doctors and you heard that from the stand from most of the doctors on our side who testified. 04:54:01 04:54:20

Their instruction, as I read it, would also ignore the or. It says if you find that they failed to prove that Dr. D'Ayala read the warning, you must find for them regardless of B. It's not an O. That's an end of story. 04:54:40

THE COURT: I think Ms. Helm intended to have that say you must find for Bard on part A of the two-part test. 04:54:58

MR. STOLLER: Well, that's not what it says. That's not what it says. 04:55:04

THE COURT: I know you don't think it says that. But I think that's your intent.

MS. HELM: Absolutely, Your Honor. We understand there's still a question -- 04:55:11

THE COURT: So if I were to agree with them, we could rework that wording.

MR. STOLLER: Well, I think it would be a comment on the evidence in the sense that it's telling them to do something specific with the other instruction based on "read." I think as, again -- and I hate to cite you to Your Honor. But I'm going to cite you to yourself in the order that you gave on the motion for summary judgment in the *Jones* case where they made this exact argument in *Jones* where they said our treating doc, they claim said he didn't read the IFU and you went through the evidence in that case and said, look, this is not just an IFU issue. There's a number of ways these doctors get warnings from the manufacturer here. And I distinguished this and we just got this so I haven't read *Wilson* in a while but I know I read it when we did the briefing on the summary judgment, both in this case and in *Jones*. 04:55:19 04:55:36 04:55:54

And that is a much different story than we have here. There were not multiple avenues of warnings and communications there between the manufacturer and the user that there are in 04:56:08

this case. That simply does not apply here on the facts of this case that are far different. 04:56:12

THE COURT: All right. I understand that argument.

Final word, Ms. Helm.

MS. HELM: Yes, Your Honor. At the risk of repeating, that issue was not raised in the *Booker* case, the issue that was addressed in *Jones*. 04:56:25

Also, the evidence --

THE COURT: But the question is whether it's been raised by the evidence in the trial. 04:56:37

MS. HELM: Fair, Your Honor. The only -- and expert testimony is not always required but it is often considered for complicated instructions. And if you look at the evidence in this case, the expert who testified about the warning was Dr. Hurst and every single question to Dr. Hurst, was this information in the IFU? Did this IFU meet the expectations of physicians? If a company like Bard didn't do a long-term clinical study, would you expect it to say so in the IFU? If a company like Bard -- 04:56:53

THE COURT: You've read enough examples. 04:57:18

MS. HELM: Okay. My horse is dead, Your Honor.

THE COURT: Pardon?

MS. HELM: My horse is dead.

THE COURT: But where you started on that thought was they don't have to have an expert and there has been other 04:57:30

evidence that has been presented to the jury that Bard didn't send a Dear Doctor letter, didn't advise its salespeople to notify them. 04:57:34

So I don't think I can conclude there's no evidence with which a jury might find there were other methods to communicate. 04:57:44

MS. HELM: That is fair, Your Honor. But to the extent that they are going to rely on the adequacy of the IFU, it's our position, and the evidence shows, that there is no evidence that Dr. D'Ayala read the IFU. 04:58:01

So for them to stand up at closing and say the IFU was defective, the IFU was defective, this wasn't in the IFU, all of the testimony that I was just reading to you under Georgia law, if Dr. D'Ayala didn't read the IFU, there's no causation there as a matter of law. 04:58:19

THE COURT: From the IFU?

MS. HELM: Correct, Your Honor.

THE COURT: Well, okay. I understand the parties' positions. I will look at this case. It does seem to me, Ms. Helm, that you will be free to make exact that argument. 04:58:30 We try to emphasize the need for proximate cause and you can make the point if he did not read it, it could not have proximately caused the injury.

It also seems to me that if I were to follow that line, would he need to change this instruction to say something 04:58:47

like if he didn't read the IFU, then you can't rely upon the IFU as one of the methods by which the warning was inadequate but you may consider others. That is getting to be a pretty detailed comment on the evidence. But I will read the case and take into account the arguments you've made. 04:58:50 04:59:09

MR. STOLLER: Again, Your Honor, I just make a point. I don't think the testimony supports what they said about Dr. D'Ayala and, again, you've heard it. There's many sources of these warnings.

THE COURT: Okay. Any other comments on strict liability, failure to warn? 04:59:24

MS. HELM: Your Honor, I do have a copy of Dr. D'Ayala's transcript if you would like it.

THE COURT: I've got every day's transcript on my computer. 04:59:35

MS. HELM: Actually, these are the videos so they are not in the transcript.

THE COURT: Oh. I've got him, too. I've got him on my iPad.

MS. HELM: Okay. 04:59:43

THE COURT: Thanks.

I'm keeping all of these depositions so I can go back and read them again in my leisure time.

Okay. The next instruction is negligent design defect. Any comments from either side? 04:59:59

MS. LOURIE: None from us. 05:00:05

MS. HELM: No, Your Honor.

THE COURT: You all can sit down as you talk. Pull the mics down and talk right into them.

How about negligent failure to warn? I assume the same instruction is requested by defendant on that one. 05:00:15

MS. HELM: Yes, Your Honor. I won't repeat my argument.

THE COURT: Any other arguments on negligent failure to warn? 05:00:31

MS. LOURIE: No, sir.

THE COURT: Okay. How about comparative fault, pages 20 and 21?

MS. LOURIE: Yes, sir. I thought on last Thursday that we had agreed to add in paragraph D the language from the pattern charge in the first sentence. We were going to say in order to show that Dr. Amer's -- 05:00:42

THE COURT: Let me just cut you off, really so I can explain why we didn't do that and you can respond.

We looked at the Georgia pattern jury instruction and it's not in the pattern jury instruction in that place. 05:01:05

If you look at C and it talks about whether Dr. Amer treated Ms. Booker in an ordinarily skillful manner and D it seems whether the question is whether if he didn't, his negligence was the proximate cause. 05:01:41

MS. LOURIE: So you're saying that you split it up between C and D? 05:01:53

THE COURT: Well, that's the way it was when we proposed it. I'm sorry. Just a second. I need to check with my lawyer. 05:02:02

THE CLERK: Do you have the pattern jury instruction in there?

THE COURT: No. It's not in the comments.

Anyway, go ahead and you will want that back in I take it? 05:02:29

MS. LOURIE: Yes, sir. We would like for D to read --

THE COURT: Well, let me interrupt you. I just had the other thought I had. The first sentence of D says: Bard must present expert testimony to prove what's in that sentence 05:02:43 which, if we add negligence, it would say, Bard must present expert testimony to prove negligence and yet C, which is from the pattern instruction, says they don't have to.

MS. LOURIE: That they don't have to.

THE COURT: Yes. It says expert testimony is usually 05:03:01 required to overcome the presumption.

MS. LOURIE: That's a different concept, Your Honor. It specifically says in the pattern charge that you have to present expert testimony to show negligence on the part of a non-party. 05:03:19

THE COURT: Where are you reading from? 05:03:20

MS. LOURIE: 62.300.

THE COURT: Well, don't you agree the last sentence of C, which I think is from the pattern instruction, suggests you don't always have to use expert testimony to prove 05:03:37 negligence which is breach of the standard of care?

THE CLERK: In the presumption to overcome the standard of care it says expert testimony is usually required to overcome the presumption. We have it correct.

THE COURT: We think we're being true to the pattern 05:04:10 instruction but if we're not, I absolutely -- I don't know how we can say in C it's usually required to prove breach of the standard of care and in D say you have to use expert testimony to prove breach of the standard of care.

MS. LOURIE: So under Georgia law, you always have to 05:04:26 have expert testimony for medical negligence unless it's pronounced results. This is my med mal attorney back here.

THE COURT: That's fine. I guess, so are you thinking that the standard jury instruction -- that the Georgia model jury instruction is incorrect? I mean if you're right, 05:04:44 then --

MS. LOURIE: I'm not sure if C is from a pattern jury charge or not.

MS. HELM: Your Honor, I think -- if I may. I think the distinction is that the pattern charge says expert 05:05:02

testimony is usually required to overcome the presumption of negligence. And then it says that expert testimony is required for proximate cause. 05:05:06

THE COURT: That's the difference between C and D in this instruction. 05:05:18

MS. HELM: Exactly, Your Honor. So it's our position that those instructions -- it mirrors the instruction.

THE COURT: Let me look at the pattern for a second.

Our paragraph C and D follow the standard instruction which is why we didn't make the change you had recommended. 05:05:58

MS. LOURIE: So you're saying that D follows the pattern instruction?

THE COURT: Yes. C and D. The pattern instruction, when it's talking about negligence, says expert testimony is usually required. Pattern instruction, when it's talking about proximate cause, says Bard must present expert testimony. 05:06:15

MS. LOURIE: It says in D you have to show that the non-party was negligent and that his negligence was one of the proximate causes of the injury.

THE COURT: Where are you reading? 05:06:37

MS. LOURIE: The first sentence: In order for Bard to show that Dr. Amer, a non-party, was negligent and --

THE COURT: What are you reading?

MS. HELM: You're reading the wrong page.

MS. LOURIE: I'm reading from my charge. My 05:06:50

stipulated request to charge number one. 05:06:54

THE COURT: Oh, I thought you were reading from what I submitted to you yesterday.

MS. LOURIE: I'm sorry. This is what tracks the language from the jury charge. 05:07:03

MS. HELM: No. I don't think it does.

THE COURT: What's the number on that, Jeff.

THE CLERK: 62.300.

THE COURT: 62.300 we think is the Georgia pattern instruction that this follows so why don't you look at that, 05:07:21 Ms. Lourie, and we can talk about that tomorrow if we're misreading that pattern instruction. That's the reason we didn't make that request.

MR. STOLLER: That's the reference to C as well is 62.300. Because I know that C is. 05:07:35

THE COURT: Yes, they are both in there.

THE CLERK: They are both the standard of care and causation.

MR. STOLLER: Thank you.

THE COURT: Okay. So look at that. You can sure 05:07:49 raise it tomorrow if you think we're misrepresentation reading that standard instruction.

Did you have other comments, plaintiff's counsel, on comparative fault?

MS. LOURIE: No. 05:08:05

THE COURT: How about from defendant? 05:08:05

MS. HELM: No, Your Honor.

THE COURT: Okay. The next one is intervening cause or superseding cause.

Ms. Lourie, I think you've given us a proposal which 05:08:17
I haven't read yet. Do you want to explain what you're recommending?

MS. LOURIE: Well, Mr. Stoller drafted that so I'm going to let him explain.

THE COURT: That's fine. 05:08:28

MR. STOLLER: I will, Your Honor. In particular, here's the concern we have with the instruction that you drafted which is that it suggests that an intervening act which this becomes a superseding cause, can apply only to a part of an injury. 05:08:45

And under -- both in their statement and in Georgia law, it's an intervening act that cuts off proximate causation. It can't be part of the cause for part of an injury. You can't take a broken arm and say, well, the intervening cause is partly at fault and Paul Stoller is partly at fault. 05:09:06

THE COURT: What about your hypothetical that you gave when we were here last?

MR. STOLLER: I'm sorry, the hypothetical that I gave last time where the neighbor comes in and cuts -- I've broken my arm in a car accident and neighbor comes in and cuts off my 05:09:23

arm. Well, the injury there -- 05:09:26

THE COURT: At the wrist.

MR. STOLLER: -- at the wrist. That's fine. Wherever he does it.

THE COURT: That's important because the broken arm remains. 05:09:34

MR. STOLLER: I would agree with you, Your Honor, and I would say that those are two distinct injuries. The loss of my hand is an injury that the question under proximate cause and under intervening cause or intervening act becoming a superseding cause as to that injury is one of foreseeability and did the car accident that caused the harm to my arm, is the subsequent harm the cutting off of my hand a reasonably foreseeable act or proximately caused by that? In that case, I would argue the answer is no. 05:09:47 05:10:08

But if Ms. Lourie is the one who hit me in the car accident, she is still responsible for the injury up to my wrist. That superseding intervening act doesn't change that so it's not part of the injury. It's a distinct injury and if you read the -- 05:10:23

THE COURT: Let's assume hypothetically for a minute that one of the consequences of the broken arm would be that you lose the use of your thumb. I think what you're saying is that injury for lost use of the thumb could not be attributed to Ms. Lourie if she's the one that hit you because the 05:10:42

neighbor's intervening act of cutting off your arm at the wrist superseded in which event part of the injury she caused is being eliminated by an intervening superseding cause. 05:10:46

MR. STOLLER: It's -- the statement uses the word "harm" and it depends upon how you're going to interpret the singular of that word. If everything done to me is a single harm, I don't think that is correct because I don't think it's a correct interpreted as a single harm. 05:11:02

I think in your analogy, I have a harm which is that I have a broken arm and I also have a harm which is a loss of the use of my thumb. And when somebody comes with a hedge whacker and cuts off either my hand or a thumb, I still have a separate injury for the pain and suffering and medical treatment to my arm other than now the loss of my hand or the loss of the thumb, but I think they are distinct injuries. 05:11:20 05:11:42

THE COURT: So how would you instruct the jury in that case on intervening cause?

MR. STOLLER: In your case I would take out the references that -- well, what we've tried to do in the instruction we gave you was take out all or part and talk about it as injury rather than injuries. It's not a plural concept, it's a singular, and break it down to the singular. And we'll talk about this I think when we get to the verdict form. But to the extent that the jury sits back in the jury room and is making determinations of what has been proven on our causes of 05:11:55 05:12:13

action, they are going to look at and I'm going to probably not get this all right in this case but they will look at Ms. Booker and say she had a filter that broke in her IVC. As a result of that, she had a perforation of her IVC. Did we prove proximate cause that the design defect or the failure to warn caused that and is there an intervening act there? 05:12:16 05:12:32

There's no allegation there is. But that is a harm and she had to have a surgery for it and so she has out-of-pocket expenses for it. She has pain and suffering associated with it. She has a separate -- 05:12:50

THE COURT: Go on to the tricuspid valve.

MR. STOLLER: Well, she has a separate problem that that filter piece migrates to her heart and the question is, was it foreseeable and we have to prove proximate causation for damages associated with different injuries. Open heart procedure, pericarditis, damage to her tricuspid valve. Those are separate and distinct injuries and the jury is going to have to determine whether we've proven proximate cause for those different injuries. 05:13:04

THE COURT: Well, so let me ask you this. 05:13:22

MR. STOLLER: I don't think you can lump them all in one because they are not singular.

THE COURT: Let me ask you this question. If the jury were to find that Dr. Kang's damage to the tricuspid valve was not foreseeable by Bard, was not triggered by Bard and was 05:13:35

sufficient of itself to cause the injury to the tricuspid valve, do you agree that the jury could say, "Oh, we are not going to hold Bard liable for the injury to the tricuspid valve"? 05:13:41

MR. STOLLER: If we cannot prove proximate cause, which is a foreseeability as you identified it, and they come in and prove that there's an intervening cause to that injury, then we have not made our case and they should not award damages on that injury. 05:13:58

THE COURT: So how is that possible outcome explained to the jury in this proposed instruction? 05:14:17

MR. STOLLER: By being singular. It's going to get -- this is going to get argued to the jury I assume and damages the way we argue most cases to the jury. Ladies and gentlemen of the jury, we've got -- we suffered several injuries here. My client had a broken leg and for that, he had to seek medical treatment on such-and-such a date and pain and suffering associated with that, but it is a jury argument. It's not something that gets resolved in the instruction. 05:14:33

The argument to the jury is going to be based on the instruction that says if there's an intervening cause for an injury. And, again, the statement talks about an intervening act as a superseding cause to a harm, singular, that you argue -- the way it's going to get argued to the jury is that they are going to say, I presume -- and I don't think we're 05:14:49 05:15:07

going to get there because we'll talk about that at the close of evidence. But I presume they would argue that, look, they haven't proven that this element of damage is something we're responsible for. This injury is something we're responsible for because -- 05:15:09 05:15:22

THE COURT: I understand. Why do you have injuries in the first sentence and injury throughout the rest of the instruction?

MR. STOLLER: Because I missed it.

THE COURT: So you would make injuries injury? Isn't that instructing the injury that there is an injury that is being claimed? 05:15:36

MR. STOLLER: Well, I think that --

THE COURT: While you're doing that, let me hear defendants thoughts on that. 05:15:49

MR. STOLLER: I can quickly tell you why. If you look down in the second or third sentence, one or more of the injuries. It's singular. They could argue --

THE COURT: Where are you pointing?

MR. STOLLER: Third sentence of our proposed instruction: Superseding cause of one or more of Ms. Booker's injuries. They could argue that the superseding cause applies to multiple injuries but -- in other words they could say that superseding cause did not -- it intervened and stopped the chain of causation as to this injury and this injury but they 05:16:04 05:16:21

are separate and distinct. Does that make sense? 05:16:23

THE COURT: Well, it seems to me what you are suggesting I say to the jury -- these are my words, not yours -- is, in effect, among the injuries claimed to Ms. Booker, if you find that Dr. Kang's action was the superseding 05:16:40 cause for one or more of those and the other elements of intervening cause are satisfied, then you should not hold Bard liable for those.

MR. STOLLER: I believe that's correct, Your Honor.

THE COURT: All right. I will read this with that 05:16:56 explanation in mind but I want to hear your --

MR. STOLLER: And there's another point that we'll need to come back.

THE COURT: On this instruction?

MR. STOLLER: On this instruction, yes, sir. 05:17:07

THE COURT: Okay. Ms. Helm, why don't you comment on this issue?

MS. HELM: I'm going to confess, Your Honor. I'm a little bit confused at what Mr. Stoller was arguing. I think we don't have any issue with the charge as written as a 05:17:18 superseding cause charge. I think Mr. Stoller is mixing up injury and injuries and I'm concerned that if I got confused, that the jury is also going to be confused by it.

So we have no issue with the charge as written.

THE COURT: Meaning as I wrote it? 05:17:38

MS. HELM: Yes, Your Honor. 05:17:40

THE COURT: All right. What's the second issue that you wanted to raise about this, Mr. Stoller?

MR. STOLLER: The sentence immediately following the elements. We tried to rewrite it as -- there's a double 05:17:46
negative in there and I think it's likely to confuse the jury so we tried to rewrite it as an affirmative sentence.

THE COURT: Okay. I understand your point on that. Okay.

All right. I'm going to think about this and read it 05:18:07
with that in mind.

Ms. Lourie?

MS. LOURIE: I don't know if you want me to address this right now. But along the lines of the superseding intervening cause analysis, it really comes into effect where 05:18:17
we're looking at the verdict form and that's where we had the real issue with this whole concept. I don't know if you want to discuss it while we're talking about it.

THE COURT: Since I can't find my copy, let's come back to that. I understand the point. Well, I guess I have a 05:18:40
copy. Tell me what your concern is.

MS. LOURIE: Okay. So our concern, I've got three arguments to make with respect to having superseding or intervening cause on the verdict form. First of all, we asked the jury, after listening to the Court's instruction, to 05:19:04

analyze liability on the part of Bard in Section A of the verdict form and when they analyzed that, they are going to consider duty, breach, proximate cause and damages. The Court will have instructed them on proximate cause and in the general sense and also on the superseding intervening cause. 05:19:07 05:19:24

So they will be considering proximate cause on that when they are making their decision on liability.

So let's say they find liability and they check one or more of the boxes "yes" in Section A. And they have already been through the -- 05:19:48

THE COURT: I think I understand your point. They wouldn't do that if they thought Dr. Kang was a proximate cause of some part of it. Is that your point?

MS. LOURIE: No. My point is they will have already considered that. 05:20:01

THE COURT: Right. I think I understand your point but that leads to the question how, then, do we reflect in the verdict form the possible outcome where they find Dr. Kang to be a superseding cause for an injury?

MS. LOURIE: Because I think you're instructing them in the instructions that if they find that he is a superseding cause of -- I'm confused on how we're going to actually word it. But if they find that he is for some part of the injury they are not to award any damages for that. 05:20:18

THE COURT: Right. So the question is, how do we 05:20:34

reflect that in the verdict form? 05:20:36

MS. LOURIE: It doesn't need to be reflected in the verdict form because they are going to be following your instructions in part A and then in part B they are not going to award any money for those -- that part of the damages. 05:20:48

THE COURT: So you're saying we should just assume that if they found Dr. Kang to be a superseding cause, that that finding is incorporated into whatever number they put in B?

MS. LOURIE: Absolutely. And then I also feel like if after they have made that full analysis of proximate cause and they have not awarded any money on line B for that part of her injury, by putting in section C, the Court is now telling them to reevaluate proximate cause and it's basically saying, oh, wait, are you sure you made the right decision in A and B? 05:21:04 05:21:27 Let's take another look at proximate cause and that's really giving the defendant two bites at the proximate cause apple so to speak.

It also, by putting a line in part C where they are allowed to designate some amount of money that they attribute to Dr. Kang when presumably they have not awarded any money for what Dr. Kang did, then the Court is going to go back and deduct that from line B. So there again, the defendants are going to have the money taken out again. So it's out twice. 05:21:47

THE COURT: Okay. I understand that point. 05:22:13

Ms. Helm, do you have thoughts on this? 05:22:17

MS. HELM: Well, Your Honor, I think that because it's -- we have more than one injury here, this issue of superseding cause as you've charged them needs to be a part of the verdict form. When I was listening to Ms. Lourie, I was 05:22:28 wondering if maybe sections B and C of the verdict form should be switched but then I'm not sure I get there. But we have one possible change to the verdict form on superseding cause but feel like in light of the evidence in this case, it should stay on the verdict form. 05:22:51

THE COURT: All right. I understand the issue you've raised and I think it's a legitimate issue. I don't know what the answer is but I want to think about that some.

MS. LOURIE: May I make one more comment, Your Honor? Well, two actually. I think I already addressed that by 05:23:07 allowing the jury to do this in part C, it's really equitable apportionment which I think I explained last week.

THE COURT: Right. I understand that argument.

MS. LOURIE: And then one more point if you don't mind. We anticipate, and I don't know because we haven't heard 05:23:25 all the testimony in the case, but we anticipate, based on the pleadings and the opening statement, that defense is going to argue more than one intervening cause. We think they are going to argue that Dr. Amer is an intervening cause and they possibly could argue that Dr. Harvey is an intervening cause 05:23:42

because he didn't leave the strut in the heart. 05:23:45

If that occurs, then --

THE COURT: Well, let's find out.

Are you going to make that argument, defense counsel?

MS. HELM: No, Your Honor. 05:23:58

THE COURT: You're only going to argue Dr. Kang as an intervening cause? Is that right?

MS. HELM: Correct. We're going to argue that Dr. Amer is a separate act of negligence that impacted Ms. Booker, the proximate cause. 05:24:11

THE COURT: Okay. I think that answers that concern.

Okay. I will think about the verdict form and the intervening cause issues that have been raised.

All right. Anything else on the superseding cause instruction that we need to consider? 05:24:31

Okay.

Assumption of the risk, page 23.

MS. LOURIE: Well, other than the fact that we don't think that that has been shown by the evidence, but I guess we'll argue that later. 05:24:53

THE COURT: Right. These are instructions to be used if they are supported by the evidence.

Any comments on that?

MS. HELM: No, Your Honor.

THE COURT: Damages, pages 24 and 25. 05:25:06

MS. LOURIE: No, sir, no objection. 05:25:10

MS. HELM: Nothing, Your Honor.

THE COURT: All right. How about punitive damages, pages 26, 27, and 28?

MS. LOURIE: No, sir. 05:25:38

MR. NORTH: Your Honor, the thing on punitive damages is we still believe Bard's proposed number 10 originally regarding the applicability of dissimilar conduct with regard to any punitive award should be given under the facts of this case. It's pattern charge 66.772. 05:26:00

THE COURT: It was number 10 that you proposed?

MR. NORTH: In our original, the joint filing of February 28, document 10254 it was page 117 and 118 in that filing.

THE COURT: Right. What is the dissimilar conduct to which this instruction would be directed? 05:26:25

MR. NORTH: I understand Your Honor may disagree with me but I believe things such as the warning letter they are going to hear about tomorrow, failure to report several particular complaints, all of this Recovery death evidence is not applicable to the design of the G2 filter implanted in Ms. Booker and they are going to try to argue to this jury to award an extravagant punitive award based on what I think is dissimilar conduct. 05:26:45

So in that way, I recognize it's a repeat of the 05:27:05

argument we made at the motion *in limine* stage but I don't believe under the law and I don't believe under the Supreme Court precedent that talks about how the punitive -- the conduct that will warn a punitive award must be directly related to a plaintiff and what occurred with that plaintiff. I don't think it's appropriate here. So I think that the jury needs to be instructed to that effect. 05:27:07 05:27:23

THE COURT: Any comments?

MR. STOLLER: Your Honor, we don't think there's any dissimilar conduct in this trial. You know our position on this. We've argued it in the summary judgment motions and we've argued it again and again but the conduct is all related to the filter that was implanted in Ms. Booker. The failures by Bard to -- from the get-go of the Recovery all the way through the G2 are highly related to what's here and they are certainly related to our claim for punitive damages in this case. 05:27:39 05:27:57

THE COURT: All right. I will consider that. I understand the argument.

MR. NORTH: Can I make one more point, Your Honor? I think this record is clear that no witness, including the plaintiff's experts, could indicate that they had any awareness of any death from a migration of a G2 filter, the filter at issue in this case. There is no evidence that the sort of migration deaths that so much of the evidence is focused on 05:28:05 05:28:23

with regard to Recovery filter ever happened with this device and I think that strengthens our position that that is dissimilar conduct. 05:28:27

THE COURT: Okay. I understand that.

MR. STOLLER: Your Honor, would you like a response from us now? 05:28:37

THE COURT: I'm pretty sure I know what it is.

MR. STOLLER: Okay. That's why I asked the question.

THE COURT: It's essentially what you just said; right? 05:28:45

MR. STOLLER: Essentially, yes. I think you've heard our case on this.

THE COURT: All right. Anything on the final instructions, the jury deliberation instructions?

Okay. Now, I've been handed several proposed instructions by plaintiff. Do you want to make any comments on those, Ms. Lourie? I think I understand the intent of them but I'm happy to hear any comments you wish to make on them. 05:29:06

MS. LOURIE: With respect to the limiting charge, I think that in light of what was brought out in evidence during cross-examination of Ms. Booker, her failure to follow up with doctors' appointments and her leaving without medical advice, since the mitigation of damages and contributory negligence defenses have been withdrawn by the defendants in this case, we feel like that we should be given this -- the jury should be 05:29:49 05:30:15

given this charge. 05:30:19

THE COURT: Is there any objection to that charge?

MS. HELM: Your Honor, I don't think there's any objection. I do think that the evidence actually went to her pain and suffering and the severity and nature of her injuries 05:30:30 rather than to mitigation. And I understood the Court's admonishment to me at the sidebar but under Georgia law, proof is required for mitigation. We weren't offering the evidence for the purpose of mitigation.

I think this comments on the evidence. I think we 05:30:48 did not assert assumption of the risk -- I'm sorry, contributory negligence or mitigation. They are not in the case.

The evidence and the testimony went to claims that are in the case. I don't think the charge is needed. 05:31:02

THE COURT: Well, my concern, Ms. Helm, is that there were two or three, maybe four specific questions asked before we had the sidebar from the medical records to suggest that Ms. Booker never came back, never reported when there was a follow-up request made. 05:31:26

I could see the jury getting back in the jury room and talking about that and saying, well, she partly caused her own problem. If she had followed up, maybe this would have been caught. And that I think under the defense that is being asserted would not be an appropriate basis for the jury to 05:31:43

reduce or eliminate her damages. 05:31:47

MS. HELM: Your Honor, alternatively, the jury could say she didn't go to the doctor. She didn't follow up. She left because she really wasn't hurting, she really wasn't suffering any pain at the time or -- 05:31:59

THE COURT: Well, but doesn't this instruction focus rather narrowly on my concern by saying there's no contention that she is at fault for her injuries in the case? You can't blame her for the injuries.

MS. HELM: Your Honor, the instruction does address your concern. I think I'm arguing that I disagree with your concern. But, yes, the instruction addresses your concern. 05:32:15

THE COURT: Okay. I'm going to give this instruction.

So Jeff, let's include that. 05:32:27

Did you want to comment on others, Ms. Lourie? I think I understand them all but I want to make sure if you have other points, to make sure we do it quickly only because it's 5:32 and Elaine has been going --

MR. STOLLER: I'll do it quickly, Your Honor. On the FDA, what I'll call the FDA instructions, which are the first three, are just to give the jury some understanding of what those terms are -- that they have heard have been used. These come from the statutes of, you know, adulterated, misbranded and understanding the obligations of a medical device company 05:32:46 05:33:02

with respect to those and what those terms mean. 05:33:05

The fourth request, testimony by Food and Drug Administration employees, is to let the jury know why they are not hearing from those folks in this trial. They have heard a lot about the FDA but they are not going to hear from the FDA 05:33:16
folks because they can't come here and testify. And you know the purpose of the limiting instruction, this is taken pretty -- if not verbatim, pretty close verbatim from your order and the FDA preemption motion.

THE COURT: All right. Defense comments on these 05:33:33
proposals?

MR. NORTH: Yes, Your Honor. We strongly object to these. First of all, I'm not sure that there has been actual evidence here that this device was misbranded or adulterated except to the extent it might be tangentially suggested in the 05:33:48
warning letter regarding complaint files. But with regard to the claims in this case as to whether the design is defective or the warning is defective or inadequate warning, I don't think there's been any testimony that it was adulterated or misbranded. 05:34:07

Secondly, I think these are argumentive, particularly on the adulterated and misbranded ones, and I think they are covered completely by the testimony. Both sides had the opportunity to put on testimony as to any defect in the product and there's a general standard on design defect and warning. 05:34:29

I also don't think it's appropriate to instruct the jury about the FDA not being able to give testimony. I think that raises more questions with the jury than it answers. I mean, you know, both sides could be faulted by the jury. It's not a one or another side that the jury might necessarily blame for not bringing in an FDA person, so I think that is inappropriate. 05:34:33 05:34:51

The last one seems to be a fair statement of what the Court has ruled in the past but we have been very, very careful I think in this case to use the word "clearance," to avoid the word "approval" and there's been a full explanation by our expert on what that meant and the plaintiffs had the opportunity to present their own and they did not. 05:35:14

THE COURT: Okay. I understand the parties' positions. 05:35:33

MR. NORTH: And I've got a couple of charges to give the Court.

THE COURT: Okay. I think I've covered all of the plaintiff's proposed charges.

MR. STOLLER: Yes, we have. 05:35:42

THE COURT: Okay. Let's quickly take up the defendants'.

There's two of them; is that right?

MR. NORTH: Yes, Your Honor. Number 11 and number 12. 05:36:13

THE COURT: All right. So the question, plaintiff's counsel, is, do you object to the first proposed instruction which, since it's not in the record elsewhere, I'll read. And, incidentally, plaintiff's counsel, actually both of you, would you please just file a notice in the docket attaching your proposed instructions that we discussed today so it's in the record? 05:36:25 05:36:36

MR. STOLLER: Yes, Your Honor.

THE COURT: But this one would say that under Georgia law, whether the FDA instituted any regulatory action is a factor you may consider. 05:36:47

Is there an objection from plaintiff on that?

MS. LOURIE: Our objection would be that that is already contained in the charge twice. It doesn't say under Georgia law but in the Georgia pattern instruction on design defect, strict liability, it's prong 13 and prong 13 is further explained in what is currently the last paragraph of the charge. 05:37:06

THE COURT: So page 14, paragraph 13 you're referring to and then the paragraph on page 15 is what you're referring to, Ms. Lourie? 05:37:39

MS. LOURIE: Yes, sir.

THE COURT: Why isn't it covered by that?

MR. NORTH: Your Honor I think it's a slightly different concept. There's one thing -- this is talking about 05:37:58

the manufacturer's conduct in complying. The ***Browning v. PACCAR*** case under Georgia, looking at from it the agency perspective, says that the absence of a regulatory action with regard to the design of a mass-produced product is some evidence. 05:38:01 05:38:15

THE COURT: We're not talking about -- oh, I'm sorry. I understand your point. You're saying this doesn't have to do with the company's compliance. This has to do with the agency's failure to act?

MR. NORTH: Right. 05:38:32

THE COURT: Okay. I understand it now.

MR. STOLLER: Your Honor, this goes too far. I mean, there's a pattern instruction. It lists out the relevant factors for the jury to consider. This is effectively a comment on the evidence and telling them that if they haven't seen anything here that somehow that the design wasn't defective or negligent is particularly inappropriate in a case like this where we went through 510(k) clearance and not a PMA. 05:38:44

I mean, we had a long set of briefing and argument on what does -- what do the actions of the FDA mean in this case, and an instruction like this would suggest that somehow the FDA was looking at this device and monitoring it for its safety and effectiveness of the design, which we all know is simply not the case. This goes way too far. To the extent the jury needs to -- is allowed to consider the regulatory conduct, we believe 05:39:02 05:39:20

that is already baked into the pattern instruction that you're giving, plus you're giving the supplemental pattern instruction that addresses, you know, what -- well, the relevant regulatory considerations here. 05:39:24

THE COURT: Okay. 05:39:38

Mr. North, any brief comment on your proposed 12? I understand why you're giving it or why you're proposing it.

MR. NORTH: Right, Your Honor. I just think the jury needs to be -- it need to be clear. I mean, the Court made its ruling after our regulatory expert has been excused and we can't get her back at this late point. And I think the legal consequence of a warning letter needs to be made clear to the jury. 05:39:54

MR. STOLLER: Suffice to say, Your Honor, we disagree. We think it's, again, an improper comment on the evidence in the case and the value or the lack thereof of that letter in front of the jury is something that they are to determine on its face. 05:40:09

THE COURT: Okay.

I understand the parties' positions. 05:40:24

What have we left out? Is there anything we have not covered?

MR. STOLLER: I think you've covered everything from us, Your Honor.

MR. NORTH: You have with respect to the jury 05:40:33

instructions, Your Honor. There's another matter that is of great concern to us. 05:40:36

The Court has instructed the parties to give each other 48 hours notice regarding witnesses appearance and we have been doing that religiously until now and plaintiffs did, too, in all fairness, but they have declined to tell us if they are bringing anybody for rebuttal by saying they don't know yet and they have to know if they are going to bring someone, who it may be, and I think we're entitled to notice. 05:40:46

MR. LOPEZ: He did ask me this morning, Your Honor. I told him, I said, "Look, I have to wait for the day." It's probably not going to be a witness. At the most it would probably be us designating maybe a deposition. We'll make that decision tonight. I mean, the case is not in yet. 05:41:03

THE COURT: Well, why don't you share with Mr. North the possibility so at least they can be doing some preparation tonight? 05:41:19

MR. LOPEZ: I will.

THE COURT: Tell him what the possibilities are. That doesn't mean you have to use them, but at least he can do some preparation. 05:41:27

MR. LOPEZ: We huddle up every night, Your Honor. We can do that.

MR. NORTH: Can I assume then that there's no live witness tomorrow? 05:41:34

MR. LOPEZ: We may -- someone that is on the subpoena list. It's not going to be an expert. It's not going to be an expert. At most it would be someone that's on the subpoena list for -- Bard employee or it would be another video. 05:41:35

MR. NORTH: Your Honor, the only other thing is at some point -- and I know now is not the time again -- I would like to make my Rule 50 motion. And I will be brief when that time comes. 05:41:50

THE COURT: How brief?

MR. NORTH: I think i need 10 or 15 minutes to make a record. 05:42:01

THE COURT: All right. We're not going to do that now.

MR. LOPEZ: Your Honor, what's our schedule? Is there a chance we're going to argue tomorrow? 05:42:09

THE COURT: Argue what?

MR. LOPEZ: I mean, do our final argument tomorrow?

THE COURT: Of the case? Well, it depends, I suppose, on how much additional time defendants take.

You've got enough time remaining. You could take all day tomorrow. How much time do you think you're going to take? 05:42:30

MR. NORTH: We will not take all day because I want to save some time for closing and rebuttal and whatever. I suspect that we'll go at least until after lunch, Your Honor.

THE COURT: Okay. But if you finish shortly after 05:42:44

lunch, we would have time for argument tomorrow; right? And I don't want to lose that afternoon. If the evidence ends at 1:30, I don't want to say, "Go home for the day, jury," because we have been very careful trying to schedule in that time. 05:42:49

MR. LOPEZ: I just don't -- I don't want to give my argument and then they are halfway through theirs and they get to go home. 05:43:04

THE COURT: Well, that is an issue we've got to deal with, as I think I raised that before, about the possibility that we could end up splitting the argument overnight. Some lawyers love to have the jury think about their argument overnight. 05:43:17

MR. LOPEZ: Your Honor, are you okay if more than one person does, like, different parts of the argument? Like someone does the opening and someone does the rebuttal on plaintiff's side? 05:43:33

THE COURT: I don't have a problem with somebody doing the first argument and somebody doing the rebuttal argument, somebody else. That's okay. We shouldn't have tag team on the main argument. 05:43:45

MR. LOPEZ: No. No. And then punitives could be someone different?

THE COURT: Yes. That's a separate part of the trial.

So I'm going to ask you to be as -- your best guess, 05:43:53

Mr. North, as to how long you think the evidence will go tomorrow? 05:43:57

MR. NORTH: I would suspect it will go until 2 o'clock to 2:30, Your Honor, at least.

THE COURT: How many witnesses do you have? 05:44:05

MR. NORTH: We have two but they are both very important witnesses.

THE COURT: Well, on the possibility that we could get done earlier, you should be prepared to argue tomorrow and what that means is that I will get you the final jury 05:44:19 instructions before the noon hour. I mean, I may not -- we may not have all the headings changed and things because I'm not going to have Nancy stay and do that tonight, but we'll get you the final jury instructions tomorrow morning sometime.

MR. NORTH: Does the Court have a 4:20 stop tomorrow? 05:44:43

THE COURT: We've got a 4:30 hearing tomorrow. What is it, Traci?

COURTROOM DEPUTY: Rule 16.

THE COURT: The answer is yes but if we're at 2 o'clock and we're starting argument, I may just -- 05:45:06

MR. NORTH: Would the Court instruct the jury before argument?

THE COURT: Yes. I will instruct before argument so they will have heard the instructions and that allows you to incorporate the instructions into your argument. I'm intending 05:45:24

to stop at 4:20. But if in order to get the argument done efficiently we need to kick that hearing off and go until 5, we will. 05:45:26

Okay. We'll see you -- well, tomorrow morning then we need to talk about 4327 and the SIR guidelines. 05:45:41

COURTROOM DEPUTY: Exhibit 7312.

THE COURT: Okay. Thank you all.

(Whereupon, these proceedings recessed at 5:46 p.m.)

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C E R T I F I C A T E

I, ELAINE M. CROPPER, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 28th day of March, 2018.

s/Elaine M. Cropper

Elaine M. Cropper, RDR, CRR, CCP